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Bioeconomía en América Latina y el Caribe 2015

Latin America and the Caribbean Bioeconomy 2015

Santiago de Chile 7 y 8 octubre de 2015



Session 2 / Sesión 2

State of the bioeconomy in LAC : a public policy perspective.

Strategy of Cuban Biotechnology/ Estrategia de la Biotecnología en Cuba



CUBA



***Situada a la entrada
del Golfo de México,
en pleno Mar Caribe.***



Capital: ***La Habana***

Superficie: ***110860 km²***

Total de Hab.: ***11 243 358***

Clima: ***Subtropical moderado***

T media: ***25°C***



Biotechnology in Cuba Milestones

- 1959** Triumph of the Cuban Revolution
- 1961** National campaign against illiteracy
- 1962** Cuban Academy of Sciences reactivation
- 1963** Scientific Institutes of the Ministry of Health
- 1965** National Centre for Scientific Research (CENIC)
- 1981** House No. 149 (Leukocyte Interferon)
- 1981** Creation of the Biological Front
- 1986** Inauguration of the Centre for Genetic Engineering and Biotechnology (CIGB)
- 1990-96** Investment Program
- 1992** Creation of West Havana Scientific Pole
- 52 facilities and more than 1,500 researchers

Post Revolution Social Programs

Education and Science



Literacy :

100% (since 1961)

Current average schooling:

> 10th grade

University centres:

66 (200 000 students)

Scientists:

>18 000 (15% PhD)

Science & Education Budget (% GDP):

9-14%

Public Health



Infant mortality: (1960- 2010)

37/1000 - 4.5/1000 new born

Life expectancy: (1960-2010)

62-78.5 years

Physicians per inhabitant:

1:165

Health Budget (% GDP):

9-15 %

Cuban biotech is supported by the high standard in health and education combined with the governmental priority to this sector

CUBAN IMMUNIZATION PROGRAM IMPACT 1962 - 2013

DISEASES	Year of Intervention	Year of Impact	Impact Achieved
Poliomyelitis	1962	1962	Eradicated
Neonatal Tetanus	1962	1972	Eradicated
Diphtheria	1962	1979	Eradicated
Measles	1971	1993	Eradicated
Rubella	1982	1995	Eradicated
Mumps	1986	1995	Eradicated
Whooping cough	1962	1997	Eradicated
Congenital Rubella Syndrome	1986	1989	Eradicated
Post Parotiditis Meningitis	1986	1989	Eradicated
Tetanus	1962	1992	Rate<0,1 x 10 ³ Inh.
H. influenzae type B	1999	2001	Rate<0,1 x 10 ³ Inh.
Hepatitis B<25 years old	1992	2001	Rate<0,1 x 10 ³ Inh.
Meningococcus Meningitis	1988	2001	<98% Mortality <93% Incidence

30 APRIL 2010 VOL 328
SCIENCE

Paul K. Drain and Michele Barry*

*Cuba, best conditions for motherhood among developing countries, according to **Save the Children's State of the World's Mothers 2010 report***

The report, examines 160 countries - 43 developed and 117 developing ones - and analyzes the best and worst places to be a mother based on 10 factors such as the educational status, health, economic circumstances of the mothers, as well as the basic well-being of children.

Among developed countries, Norway is in first place in the rankings, followed by Australia, Iceland and Sweden. USA appeared in position 28th. Cuba is in first place on the list of best developing countries

Aids and HIV

Cuba first to eliminate mother-to-baby HIV transmission

World Health Organisation hails 'one of the greatest public health achievements possible', five years into regional initiative

Lisa O'Carroll

@lisaocarroll

Tuesday 30 June 2015 12.55 EDT



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 Margaret Chan, the WHO director general. Photograph: Xinhua /Landov/Barcroft Media

Cuba has become the first country to eliminate the transmission of HIV and

Cuba has become the first country to eliminate the transmission of HIV and syphilis from mother to baby, the World Health Organisation has [announced](#).

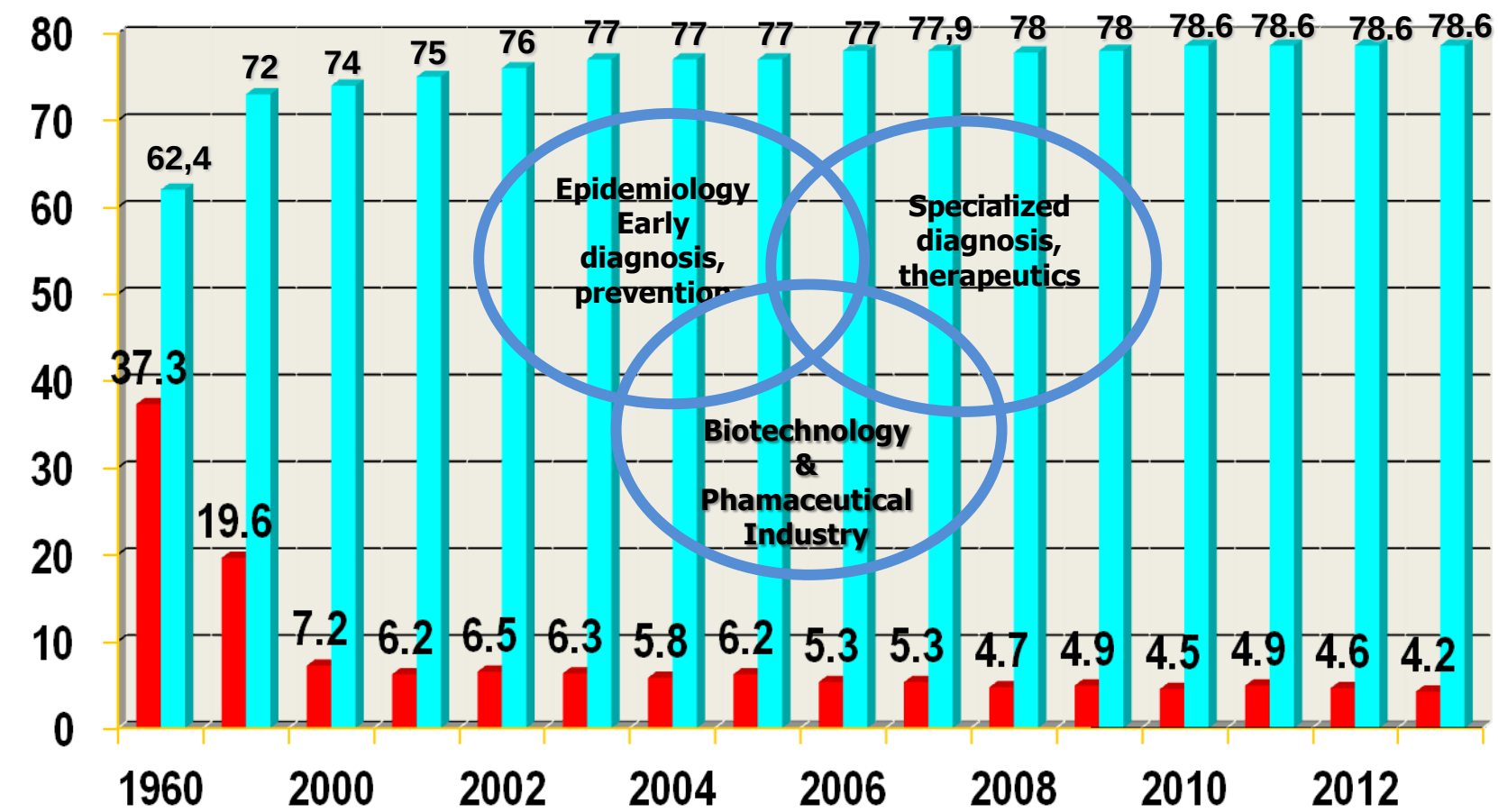
The WHO's director general, Margaret Chan, said it was "one of the greatest public health achievements possible" and an important step towards an Aids-free generation.

Advertisement



Cuban Health Program

Childhood Mortality and Life Expectancy at Birth



Enfant mortality

Life expectancy

MEGAPROJECTS

- Cancer
- AIDS
- Vaccines
- Hepatitis
- Neurosciences
- Diagnostics

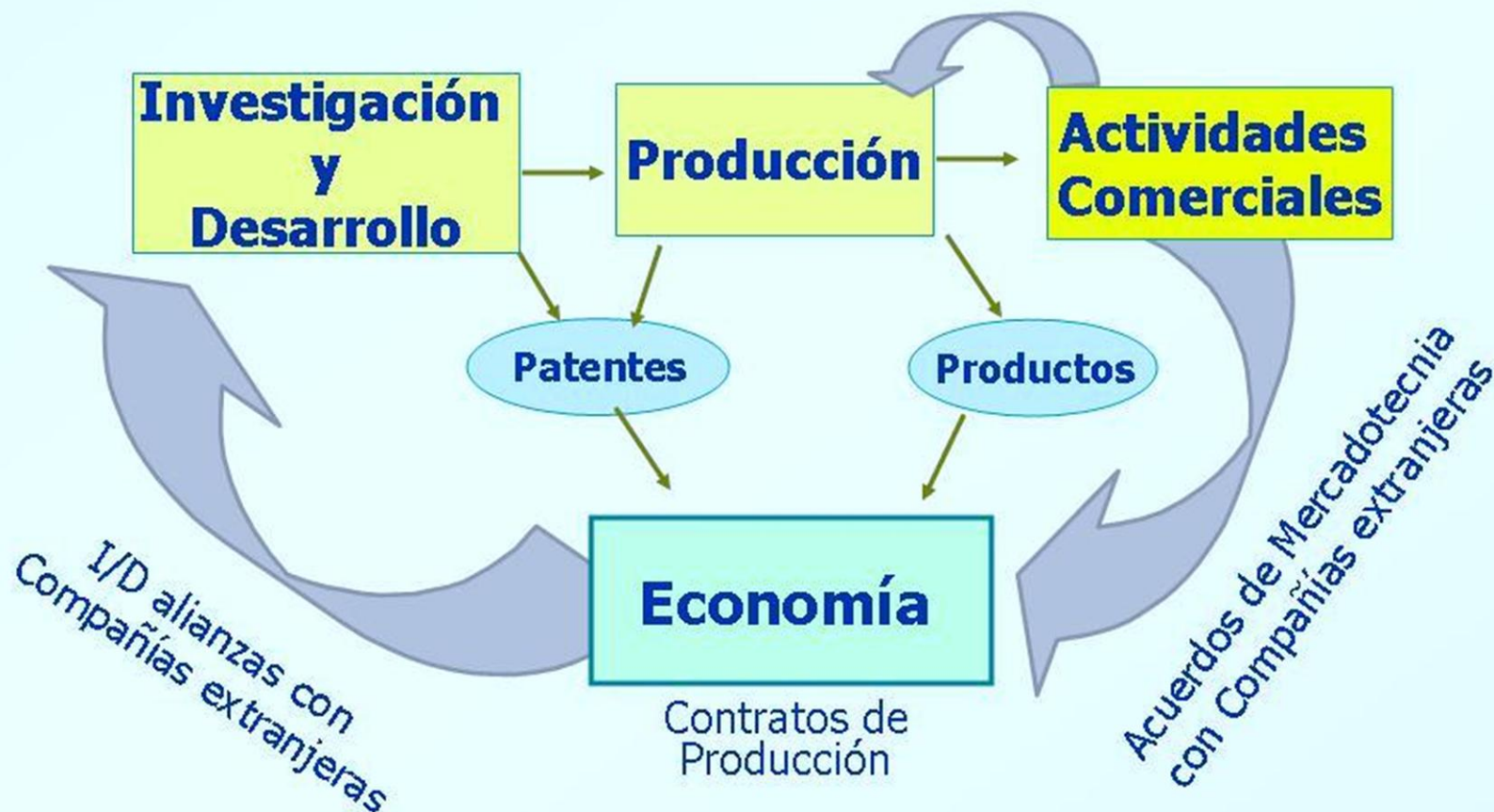
Strategy of Cuban Biotechnology

- Cuban Government: a Huge Investment
- Based on Cuban scientists and professionals
- National Health System as first priority
- “Closed cycle” strategy: fully integrated institutions, from research to post-marketing follow-up
- National collaboration instead of individual competition; coordination between institutions doing R & D and institutions applying results
- “Spin off” companies derived from scientific or production institutions
- Gaining international competitiveness: quality, production volumes, cost, novelty, joint ventures
- Intensive building capacity: R & D, Production

Ciclo: de la idea al producto

L-129,131,221

Cooperación entre instituciones cubanas





CNGM

* West Havana Scientific Pole

CIM

CIGB

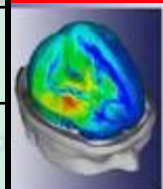
CENIC

I. FINLAY

IPK



Workers	10 356
University degree	3110
Researches	854
Technologist and Technician	1241
Master in Sciences	553
PhD	263



CIE



CIREN

CENSA



BioCen



CENPALAB



NOVATEC



Planta de Citosol



LIORAD



ATCA

Commercial products launched by the Cuban Biotechnology Program

41



1. Hepatitis B vaccine
2. Heberkinasa
3. Heberon alfa r
4. Hebermin
5. Gavac
6. SUMA System
7. DIRAMIC
8. Hebertrans
9. Culture media
10. Policosanol
11. Trofin
12. Natural products
13. Neurodiagnostic systems
14. Anti-CD3 monoclonal antibody
15. Surfacen
16. Generics
17. Melagenina
18. Neurological restoration services

18

1. Haemophilus B vaccine
2. Tetraivalent (DPT-Hib).
3. MAbs for cancer therapy
4. DPT vaccine
5. Meningococcus ACYW135 vaccine
6. Heberpenta 4+1
7. Heberpenta L
8. EPO (CIM, CGB)
9. Equipment for Neurophysiology and Neuroinformatics
10. New diagnostic systems
11. Streptokinase (w/o HSA)
12. Neurological restoration services
13. Leptospirae vaccine
14. Salmonella vaccine
15. Tethanus Toxoid
16. G-CSF
17. Allergens
18. New Trofin
19. Interferon (liquid, w/o HSA)
20. Interferon (lyophilized, w/o HSA)
21. Interferon + ribavirin
22. Gamma Interferon
23. Interleukin-2
24. PPG-plus
25. Humanized anti EGF-receptor antibody
26. New SUMA system
27. Hebernem
28. Acuabio1
29. Heberprot-P
30. Hebertrans
31. Microbiology culture media
32. New advanced generics drugs
33. Cytostatics
34. Technology transfers
35. Melagenina plus
36. Coriodermine
37. EPO plus
38. EGF viscous solution
39. Audix
40. PEG-IFN
41. Cancer vaccine

3

1. Anti-meningococcus BC vaccine
2. Heberon alfa N
3. HIV Diagnostic system

1981 - 1990

1991 - 2000

2001 - 2013

New York says that today's tensions and conflicts are characterized less by a 'clash of civilizations', than by larger groups feeling threatened

and its end-users meant that his ideas carried more influence than might otherwise have been the case.

Cuba's biotech boom

The United States would do well to end restrictions on collaborations with the island nation's scientists.

For a week after Cuba marked the 50th anniversary of its revolution on 1 January, a celebratory 'Caravan of Liberty' carried 50 people, including many university students and scientists, along the triumphal route that Fidel Castro had taken half a

Castro's interest in the fledgling industry was sparked by a meeting with Randolph Lee Clark, the former president of the M. D. Anderson Cancer Center in Houston, Texas. Castro accordingly sent six scientists to a lab in Finland to learn how to make interferon from white blood cells. The knowledge gleaned from this project has been ploughed into an industry that developed the first vaccine against meningitis B in 1985, and subsequently a vaccine against *Haemophilus influenzae* type B — the world's first human vaccine to contain a synthetic antigen.

Unfortunately, Cuba's biotech industry has also begun to feel the pinch since the early 1990s, when the end of the Soviet Union eased its generous funding. State subsidies have become more scarce, and the government has slowly pushed many scientists into the private sector. While Raúl Castro, Cuba's current leader, has encouraged the country's citizens to buy private goods — but has not allowed them

to start that conversation with the United States as possible. The United States, and the advantages could be a centre of biotech, and with Cuba's, the United States could benefit from cross-fertilization of ideas

... Cuba marked the 50th anniversary of its revolution on 1 January, a celebratory 'Caravan of Liberty' carried 50 people ...

... These people represented the health-care and educational systems of which Cubans are proud, ...

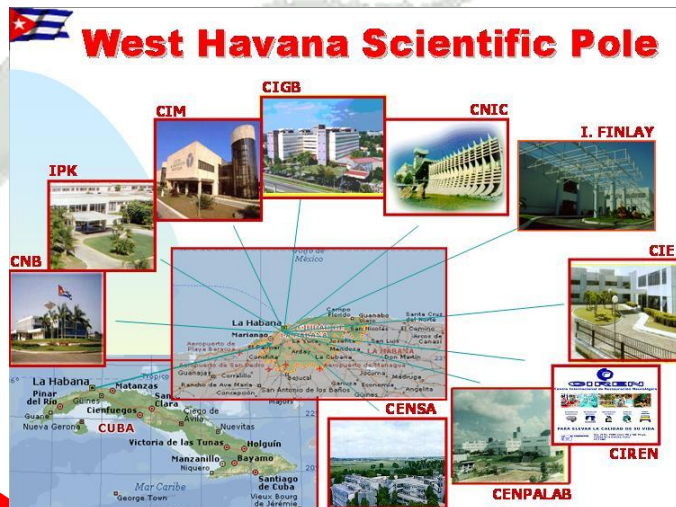
... And in no small measure the scientists in the caravan symbolize the foundation of that health-care system in the developing world's most established biotechnology industry, which has grown rapidly even though it eschewed the venture-capital funding model that rich countries consider a prerequisite.

There is increasing international recognition of Cuba's biotech industry and the revenue for the 2013-2017 period is projected to double the 2.5 billion dollars that earned in the last five years,

said Jose Luis Fernandez Yero, vice president of the country's biotech firm BioCubaFarma, in a recent TV interview.

<http://www.globaltimes.cn/content/777457.shtml>





Quimefa
Corporate
Group

- ✓ 16 LARGE PRODUCTION COMPANIES
- ✓ 8 COMMERCIAL COMPANIES
- ✓ 11 COMPANIES OUTSIDE CUBA
- ✓ 3 INTERNAL SERVICES ENTERPRISES



38 Enterprises and
more than 22000
qualified staff workers

Group of Biotech and Pharmaceutical Industry

The group manufactures generic drugs, therapeutic and prophylactic vaccines, biomedicine, diagnostic systems and high-tech medical equipment.

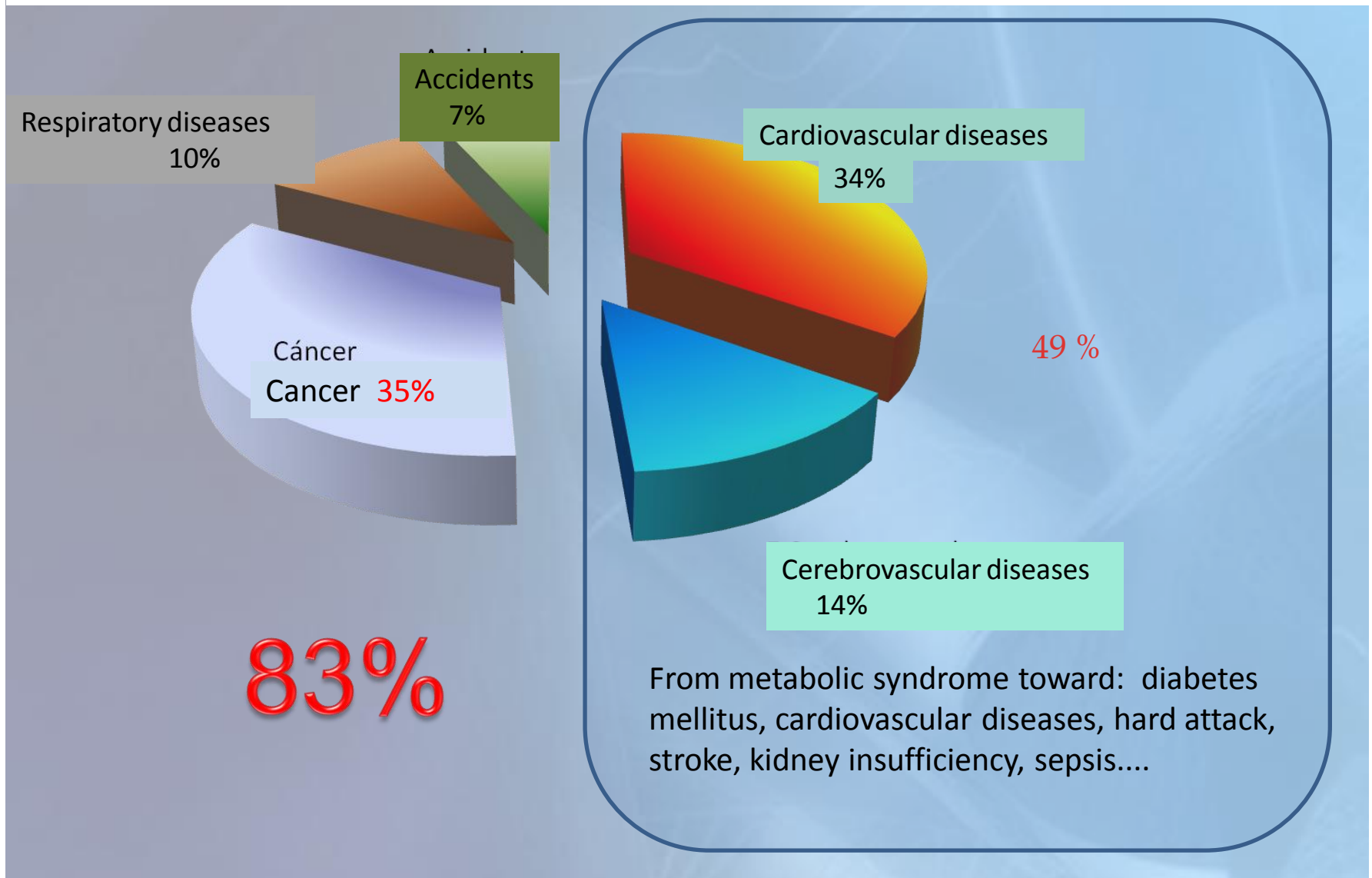
28 Noviembre 2012



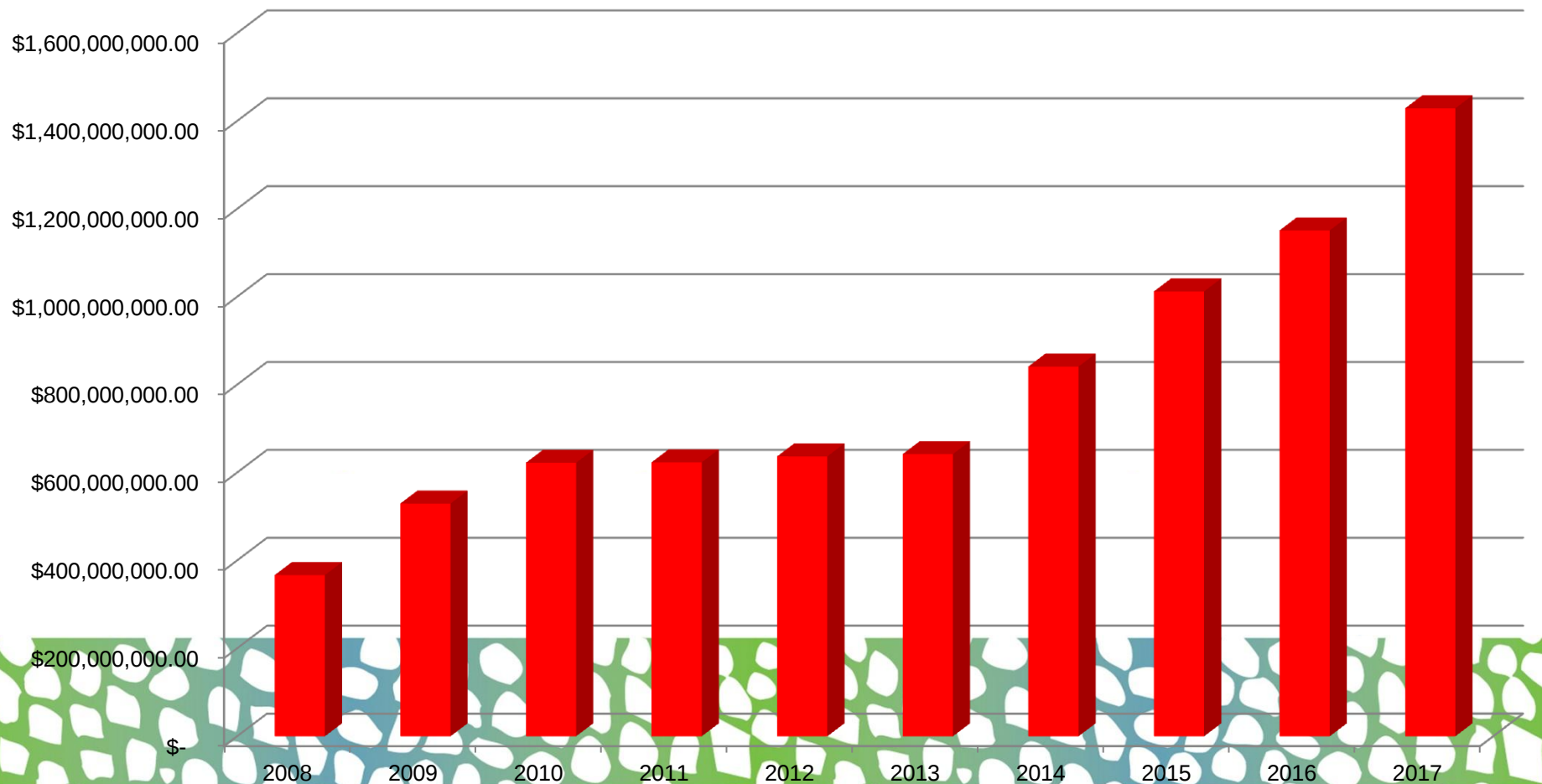
- Enterprises under the self-financing principle with the authority to import and export.
- Enterprises with the possibility of investing 10-20 % of their gross sales or net profits in research and development, as an essential form of ensuring the sustainability of the industry.
- Pay the workers according to the economic results of the entity and create stimulation funds that are awarded after complying with the State commitments and meeting the established requirements.
- Create a fund through profits (after paying taxes) that will be used in minor investments related to re-equipping, modernizing and improving quality standards.
- Create a salary fund through a percentage of the gross added value (GAV), which is distributed according to a regulation designed and approved by each entity.

CUBAN BIOTECH AS A “PROBLEM ORIENTED”

SECTOR TARGETING PRINCIPAL CAUSES OF DEATH IN CUBA



EXPORT FORECASTS 2008-2017



* TECHNOLOGY TRANSFER SOUTH-SOUTH Cooperation



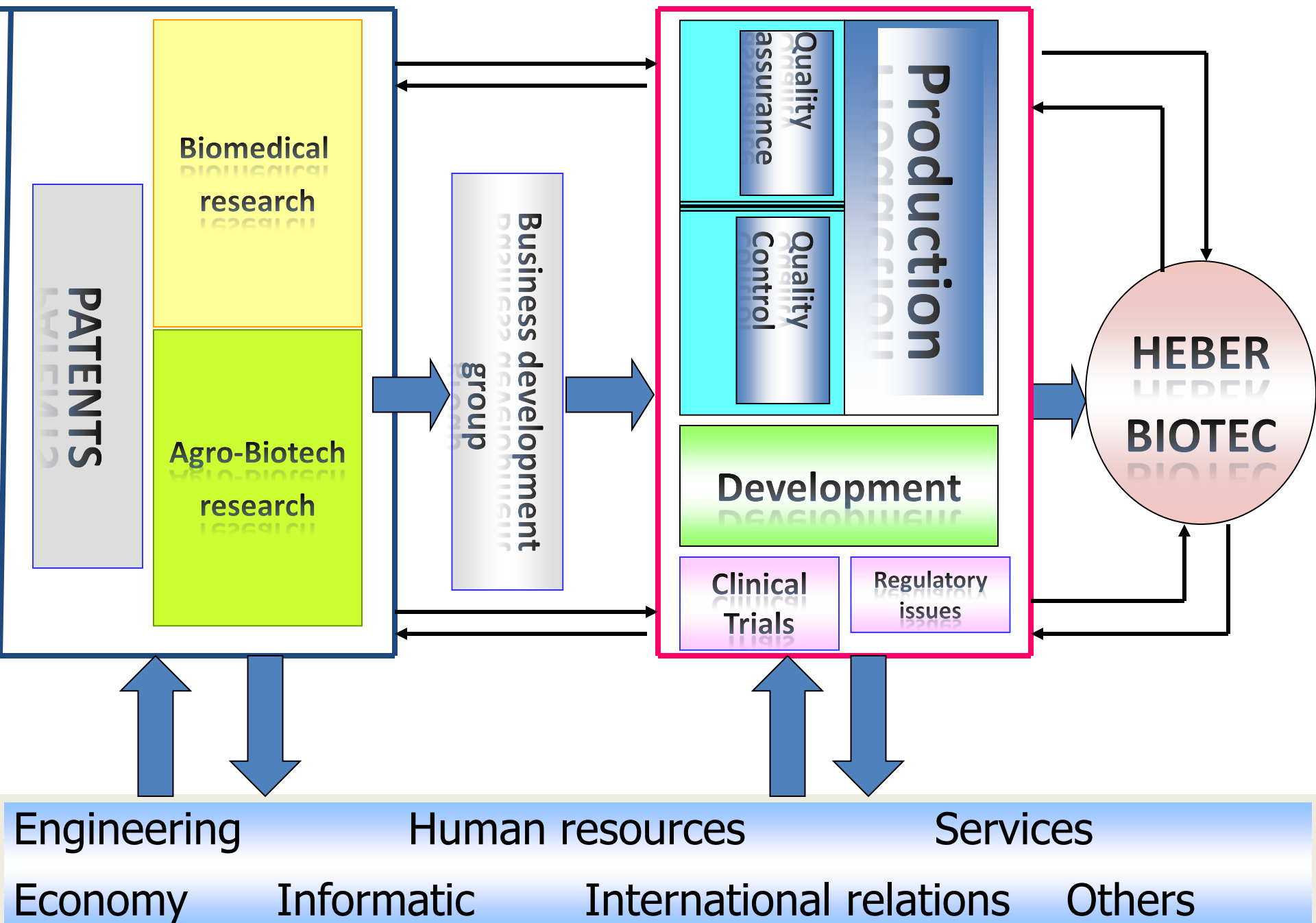


* Center for Genetic Engineering and Biotechnology, Havana, Cuba



Personnel: 1 440
Facilities: 70 000 m²

**Research Focus: Vaccines,
pharmaceuticals, diagnostics, plant
and animal biotechnology**

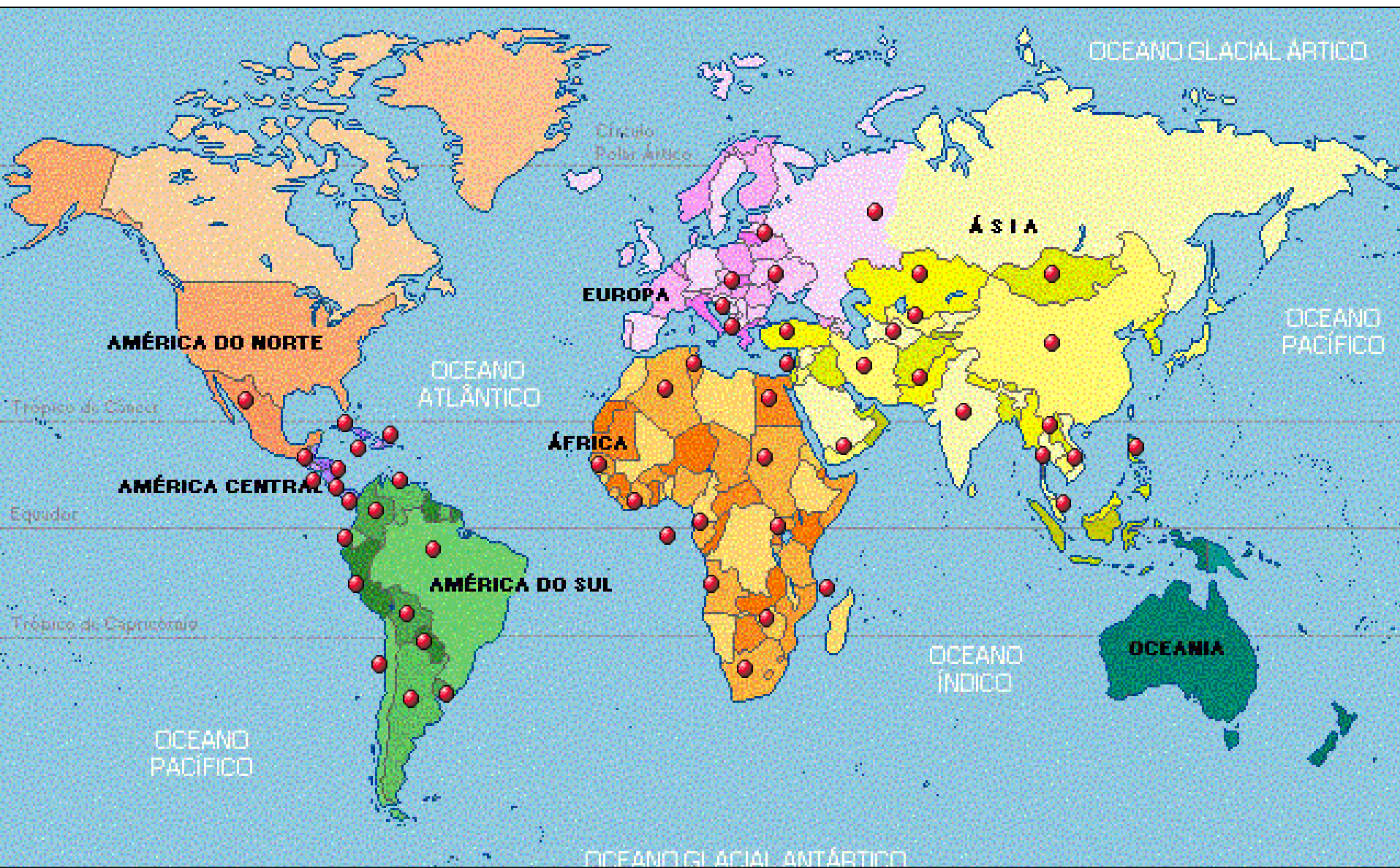


* The products of CIGB contribute to diagnostic prevention and treatment of 26 diseases in Cuba (first priority)

- Hepatitis B
- Hepatitis C
- Hib Meningitis
- Chronic Myeloid Leukemia
- Multiple myeloma
- Melanomas
- Basal cell carcinoma
- Cutaneous and no-Hodgkin Lymphomas
- Kidney cancer
- Bladder cancer
- Hemangioma of infancy
- Neutropenia
- Anemia
- Recurrent respiratory papillomatosis
- Hemorrhagic conjunctivitis
- Acute myocardial infarction
- Diabetic foot ulcers
- Cellular Immunodeficiency
- Herpes zoster
- Herpes simplex
- Burns
- Diagnosis of HIV
- Diagnosis of HC
- Pregnancy diagnosis
- Diagnosis of rotavirus
- Diagnosis of celiac disease

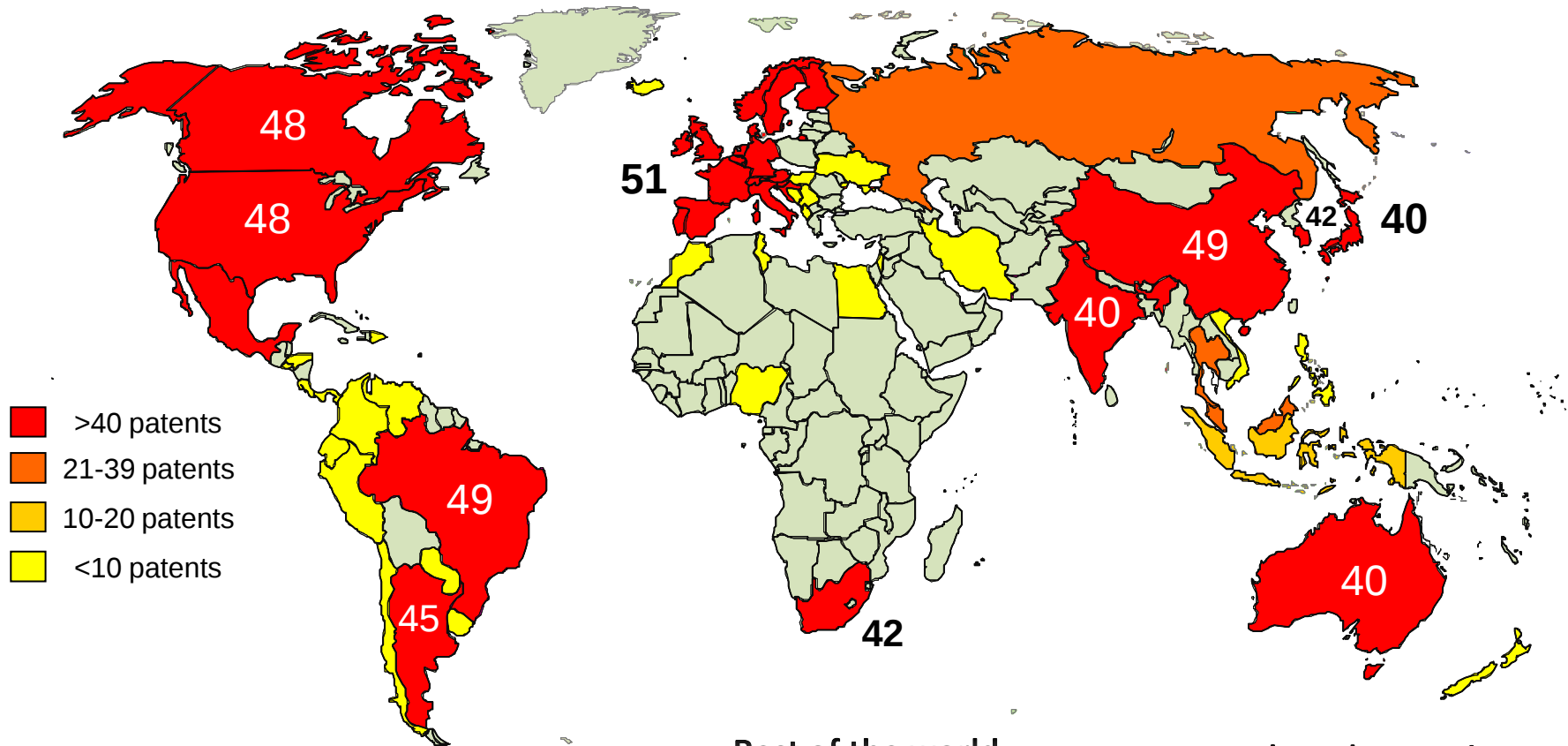


* 171 Register of 14 products in 57 countries. Exports to 40 countries

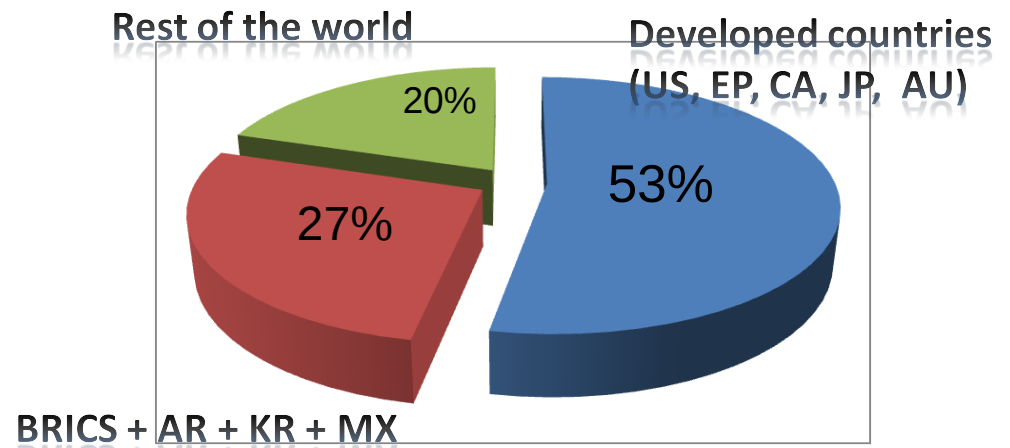


The products of CIGB contribute to diagnostic prevention and treatment of 26 diseases





60 Subject Matters
1237 Applications and Patents
68,5% Granted Patents



EXTERNAL Quality Certifications



NC- ISO 9001:2001
Registro No. 098:2008

- World Health Organization (since 2001)
- ISO 9001: 2001 (since October 2008)
- BRAZIL: ANVISA (September 2008)
- Biotik: to assess EMEA regulations (May 4-5, 2008).
- National Regulatory Authority from Ukraine (July 15-24, 2008).
- ICON Clinical Research México, SA de C.V. To assess GCP/EMEA regulations (September 17-18 2008).
- GMP in Critical Water System by Society for Systems Validation, Barcelona, Spain. (October 13- 17, 2008.)
- Dr. Erik D'Hondt; Bioven's Qualified Person, To assess EMEA regulations (April 8, 2009).
- MCC, South Africa (May 2009)
- CESIF-PRAXIS to assess EMEA regulations (September 2009).



20, AVENUE APPA - CH-1211 GENEVA 27 - SWITZERLAND - TEL CENTRAL: +41 22 791 2111 - FAX CENTRAL: +41 22 791 3111 - WWW.WHO.INT

Tel direct: +41 22 791 4050
Fax direct: +41 22 791 4971
E-mail: woodd@who.int

In reply please
refer to: QSS-CAR/IS (2009-04-14)

Your reference:

TO WHOM IT MAY CONCERN

15 APR 2009

This is to certify that the Center for Genetic Engineering and Biotechnology (CIGB), Cuba, is a supplier to UN agencies of Hepatitis B vaccine. As such, this product is reassessed by WHO for continued acceptability, in principle, for purchase by UN agencies, at regular intervals. This reassessment includes file review, monitoring compliance with specifications through testing, and facility site visits.

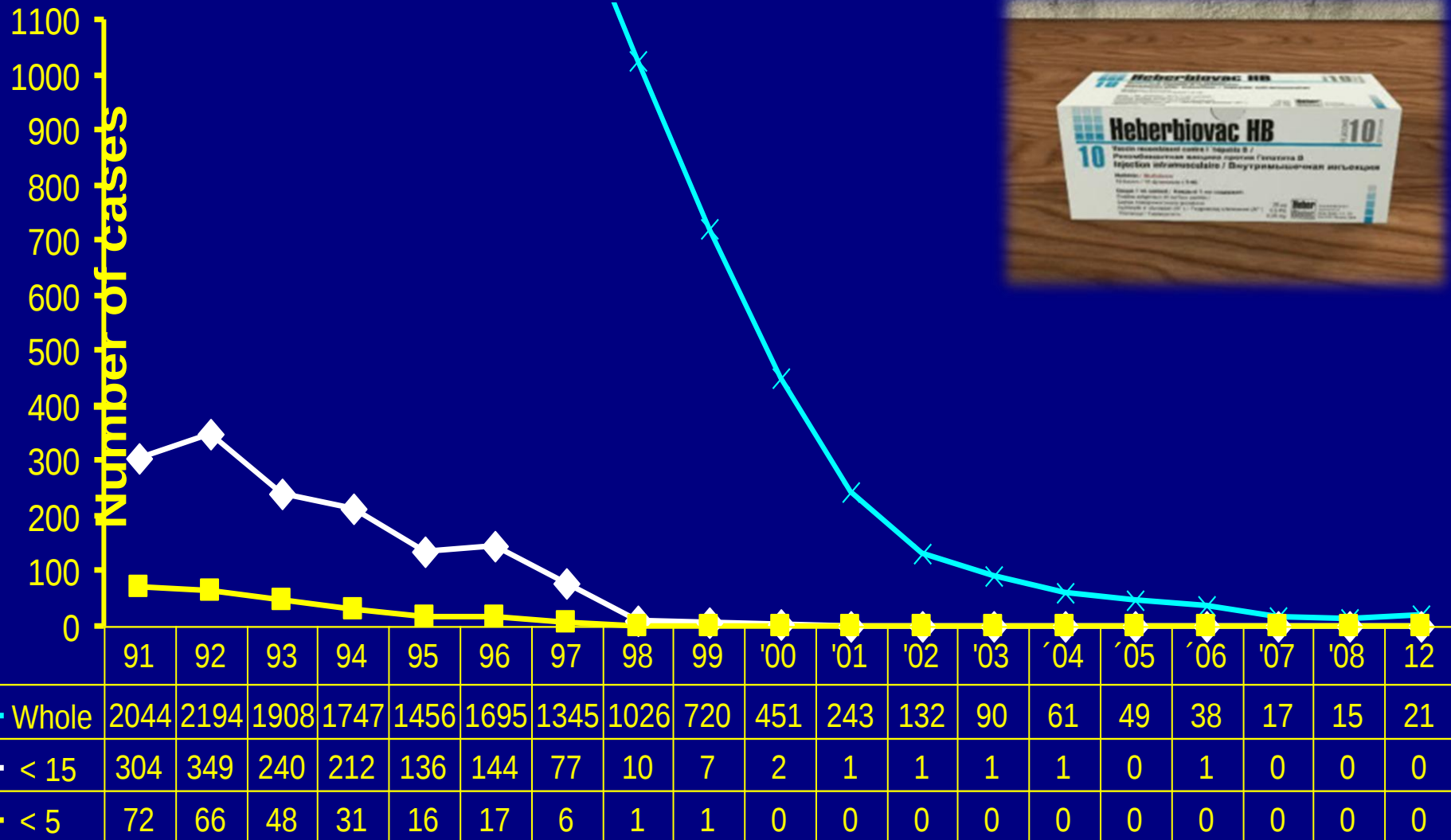
Dr David Wood
Coordinator
Quality, Safety and Standards

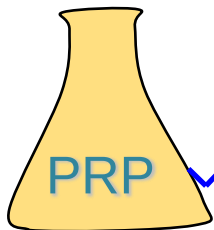


* Disease Surveillance

Incidence of acute Hepatitis B cases in children under 5 and 15 years old and adults

Cuba 1991 - 2012





Heberpenta-L

Fully liquid pentavalent DTP-HB-Hib vaccine

New Formulation

Contains all 5 antigens in a ready-to-use 0.5 mL suspension in a vial

WHO prequalification process: Working on the PSF to be submitted to WHO



* HEBERPROT-P

Worldwide unique product for the treatment of patients with advanced diabetic foot ulcers with high risk of amputation



Time 0

5 weks

3 months follow up

- ❑ Patents Granted: United States, European Union, Australia, Hong Kong, Singapore, South Korea, South Africa, Russia, China, India, Indonesia, Ukraine, Mexico, Malaysia and Cuba.

HEBERPROT-P/ Patents/Registration actions/Awards

Granted patents : EEUU, Europe, Canada, Australia, Hong Kong, Japan, Singapore, South Korea, South Africa, Russia, China, India, Indonesia, Ukraine, México, Malaysia, Argentina y Cuba. / Presented in: Brazil, Thailand and Chile.

Granted registration (26): Cuba, Algeria, Argentina, Uruguay, Dominican Republic, Venezuela, Paraguay, Ecuador, México, Libia, Colombia, Guatemala, Georgia, Ukraine, Vietnam, Philippines, Panamá, Perú, Costa Rica, El Salvador, Russia, Turkey and Belarus

Gold Medal WIPO. March 2011

Award to the best product. International Geneva Fair. April 2011



Clinical Summary (Status and trials):

Registration (20): Cuba, **Argentina***, Mexico, **Ukraine***, Russia, and other 15 countries.

***, PICS Country (Pharmaceutical Inspection Convention/Cooperation Scheme)**

Registration process (17) : Europe, Brazil, China, South Africa, among 17 countries.

Clinical trials (Seminal) of Heberprot-P

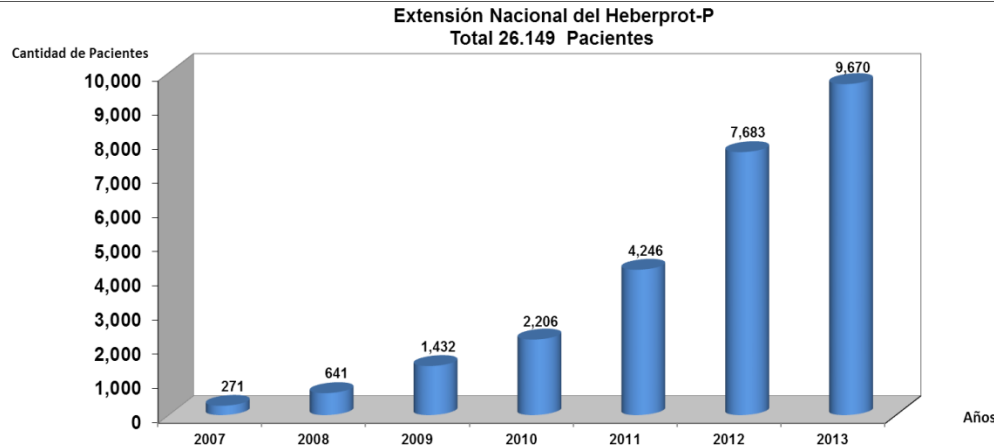
1. **Phase I:** 45 patients, 16 patients in PK trial
2. **Phase II:** Cuba, 166 patients (4 trials)
3. **Phase III:** 149 patients
4. **National Surveillance (Phase IV)**
 - Cuba: 1,851 patients
 - Argentina: > 400 patients
5. Clinical trials running in:
 - a) Europe (Phase II)
 - b) China (Phase III)
 - c) Russia (Phase III)
 - d) Cuba, MUSE Trial (Phase I)
 - e) Cuba, MRI Image (Phase I)
 - f) Cuba, Heberprogen (Phase II)



Total: > 125,000 patients

Positive results in the Cuban National Program for the Integral Care of Diabetic Foot Ulcer Patients with the use of Heberprot-P in terms of amputation risk reduction

CUBA: Treated patients, since 2007 – Dec 2013: 26 146

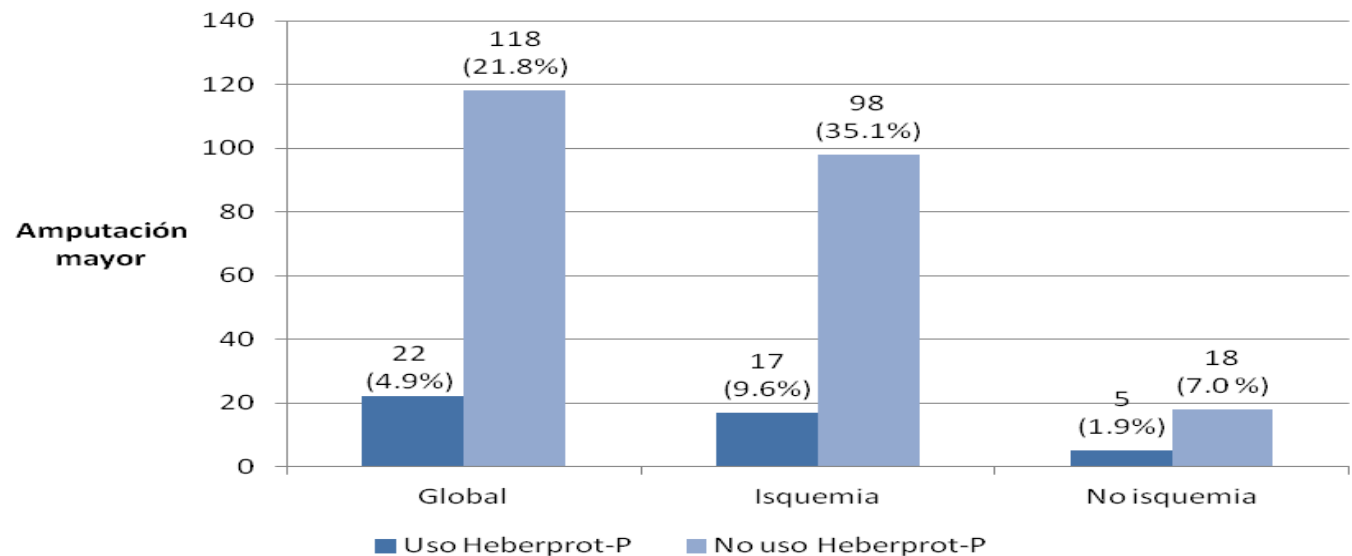


- 348 hospitals and policlinics in all Cuban province have the Heberprot-P therapy available.

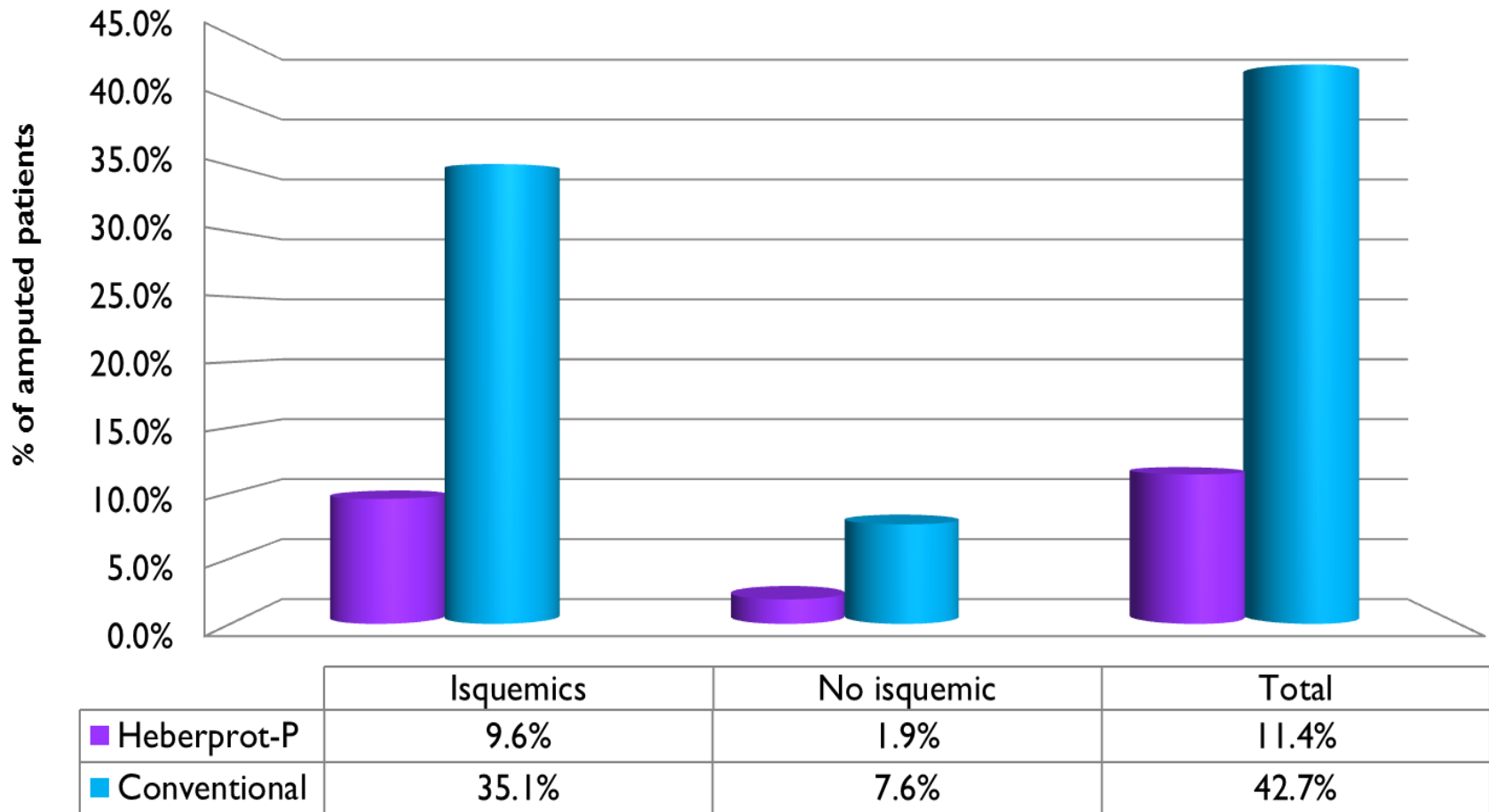
- Primary health system involving in active screening of DFU patients holding ulcers at early state.

- More than 1000 trained personnel involved in the National Net Work of the Program for the Integral Care of Diabetic Foot Ulcer Patients

Study conducted in 2011 proving the decrement of relative risk of amputation due to DFU after introducing the Heberprot-P therapy (Cuba, 2011).



Reduction of mayor amputation frequency in DFU patients (W 3-5) by the use of Heberprot-P



Study done over 1000 patients



2016-2020



- The products generated have a high positive impact in health and the food supply of the Cuban population. The first priority is to meet the people's needs
- The State offers a maximum priority to the development and **is the first line of exportable goods in Cuba**; an expression of the strong connection between science and economy. Because this industry is highly attractive for foreign capital, the strategic options for partnerships are intensified; this has a growing impact in the technological development of other domestic industries.
- The highly specialized, committed and motivated human resources have social acknowledgement for their scientific work and impact in society. They find large possibilities for professional development and promotion, through an academic training system according to individual needs and those of the industry. Their income is directly related to their results.
- The integrated and efficient output of marketing processes. The CBI increases its leadership in Third World countries. Through its novel products and high standards, it is present in First World markets and has strategic partnerships with partners from industrialized countries and emerging economies, as those belonging to the BRICS group (Brazil, Russia, India, China and South Africa).



Infectious diseases Pipeline - 2015

Vaccine Project	Laboratory	Developm	Pre Clinical	Clinical Phase		
				I	II	III
Combine vaccines						
Therapeutic Hepatitis B Vaccine						
Prophylactic Hepatitis C Vaccine						
Therapeutic AIDS Vaccine						
Acellular Pertussis vaccine						
Dengue Vaccine						
CIGB 200 – Antiviral HIV						
Dengue Inhibitors						
HIV Inhibitors						



* Cancer Therapeutic Pipeline - 2015

Project	Potential indication	Research Proof of concept	Preclinical Development	Clinical trial
CIGB-128: combination of IFNs	Basal Cell Carcinoma			
CIGB-300: anti-CK2 apoptotic peptide	Cervix			
CIGB-247: Anti-angiogenic VEGF therapeutic vaccine	PD			
Anti-GnRH therapeutic vaccine	Prostate			
CIGB-550E7: Anti-HPV therapeutic vaccine	Cervix			
Pegilated IFN, GCSF, Eritropoetin	Several tumors			
Anti-EGF receptor plantibody	Carcinomas			
CIGB-370: cytotoxic polypeptide	PD			
CIGB-166: Anti-VEGF fully human Ab and fragment	PD AMD			
CIGB-552: cytotoxic and immunomodulatory peptide	PD			
Inhibitors of IL-15	PD			

PD: pending definition



* Citoprotection, autoimmunity and vascular diseases Pipeline - 2015

Projects	Laboratory	Develop	Pre Clinical	Clinical Phase		
				I	II	III
Heberprot P (DFU)						Registered
Proctoquinasa (Hemorrhoid)						
CIGB 500 (cardio protection)						
CIGB 814 (rheumat arthritis,Chrom)						
CIGB 845 (neuro protection)						
CIGB 166 (DMAE)						
CIGB 428 (diabetic neuropathic)						
CIGB 55 (rheumatoid arthritis)						
CIGB 530 (hepatic fibrosis)						
IFN+CFB (Multiple Sclerosis)						





In collaboration with



Press release

Creation of ABIVAX - a leader in therapeutic vaccines and the first French company to sign an exclusive partnering agreement with Cuba in healthcare

Truffle Capital founded ABIVAX by merging three French companies and building on a collaboration with the Cuban Center for Genetic Engineering and Biotechnology

Paris - February 12, 2014 - [Truffle Capital](#) has announced the creation of Paris-based ABIVAX in collaboration with the Cuban Center for Genetic Engineering and Biotechnology (Centro de Ingeniería Genética y Biotecnología, CIGB). This is the first ever start-up launched on the basis of a Euro-Cuban R&D collaboration. The goal of ABIVAX is to become a global leader in therapeutic vaccines and antivirals, leveraging both its existing product pipelines and future acquisitions that are currently in negotiations.

ABIVAX specializes in therapeutic vaccines and antivirals, combining the technologies and the product portfolios of three French biotech companies financed by Truffle Capital (Wittycell, Splicosa and Zophis). An exclusive partnership agreement with the CIGB has been approved by the Cuban government and will further enrich the portfolio. The CIGB is the largest among the dozen or so subsidiaries under BioCubaFarma that specialize in the discovery, development and production of vaccines and antivirals.

<http://www.allgov.com/news/us-and-the-world/will-the-big-winners-of-normalization-with-cuba-be-us-diabetic-foot-ulcer-sufferers-150120?news=855423>

Will the big Winners of Normalization with Cuba be U.S. Diabetic Foot Ulcer Sufferers?

U.S.-Cuba Accord Should Be A Boon For Science

Cuba has world-class expertise in vaccines and environmental research to share, scientists say after last month's agreement to promote exchanges

chemistryworld

January 12, 2015 | By [Rebecca Trager](#) and [ChemistryWorld](#)

DeGette Begins Push For Approval Of Cuban Drug For Foot Ulcers

<http://denver.cbslocal.com/2015/01/07/degette-begins-push-for-approval-of-cuban-drug-for-foot-ulcers/>

January 7, 2015 4:24 PM

FAIR WARNING INVESTIGATES

As U.S. Bids to Renew Relations With Havana, Heralded Cuban Diabetes Drug Remains Off-Limits

By [Andrew Schneider](#) on January 15, 2015

U.S.-Cuba diplomatic thaw puts Mariel port back in spotlight

By Tim Johnson

McClatchy Foreign Staff January 21, 2015 Updated 22 hours ago

204,000 RESULTADOS [En cualquier momento](#)

[Todo](#) [Últimas 24 horas](#) [Última semana](#) [Último mes](#)

Renewed U.S.-Cuba Relations: Saving American Lives and Limbs?

www.huffingtonpost.com/.../renewed-uscuba-relations... [Traducir esta página](#)

Jan 24, 2015 · Heberprot-P is proof that the U.S. embargo, still to be lifted by an act of Congress, isn't just hurting Cubans. **American lives and limbs** are also, quite ...



CUBA
FUTURO DE HOMBRES DE
CIENCIAS





Muchas
Gracias