

Bio-Manguinhos

Innovation and Production
at the service of Public Health





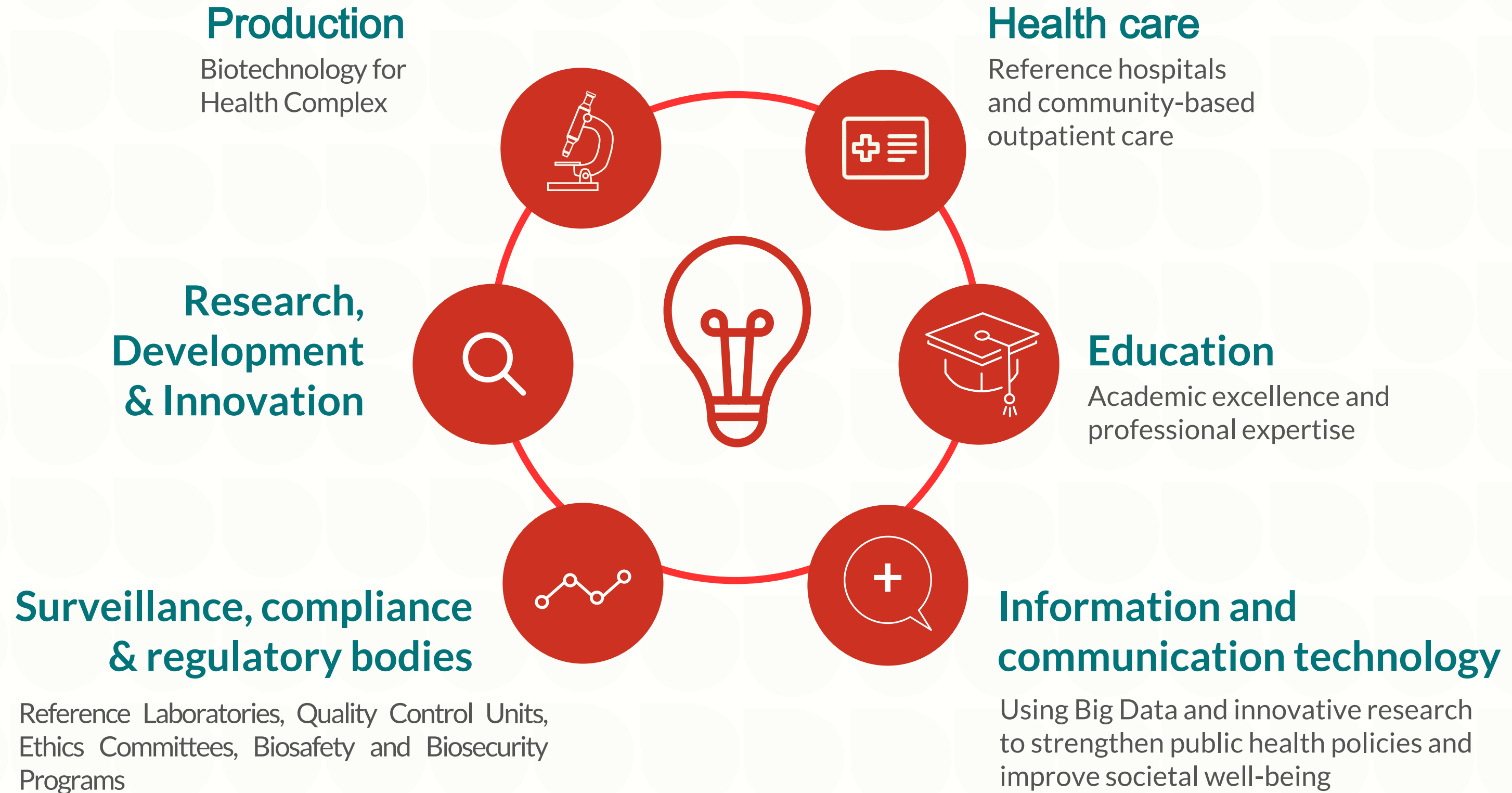
Fiocruz

Promoting health, advancing science, and
empowering society.

Fiocruz, part of Brazil's Ministry of Health, is Latin
America's leading institution in health science and
technology.

We drive innovation, generate scientific
knowledge, and deliver solutions that improve
public health and strengthen social development.

Fiocruz Ecosystem



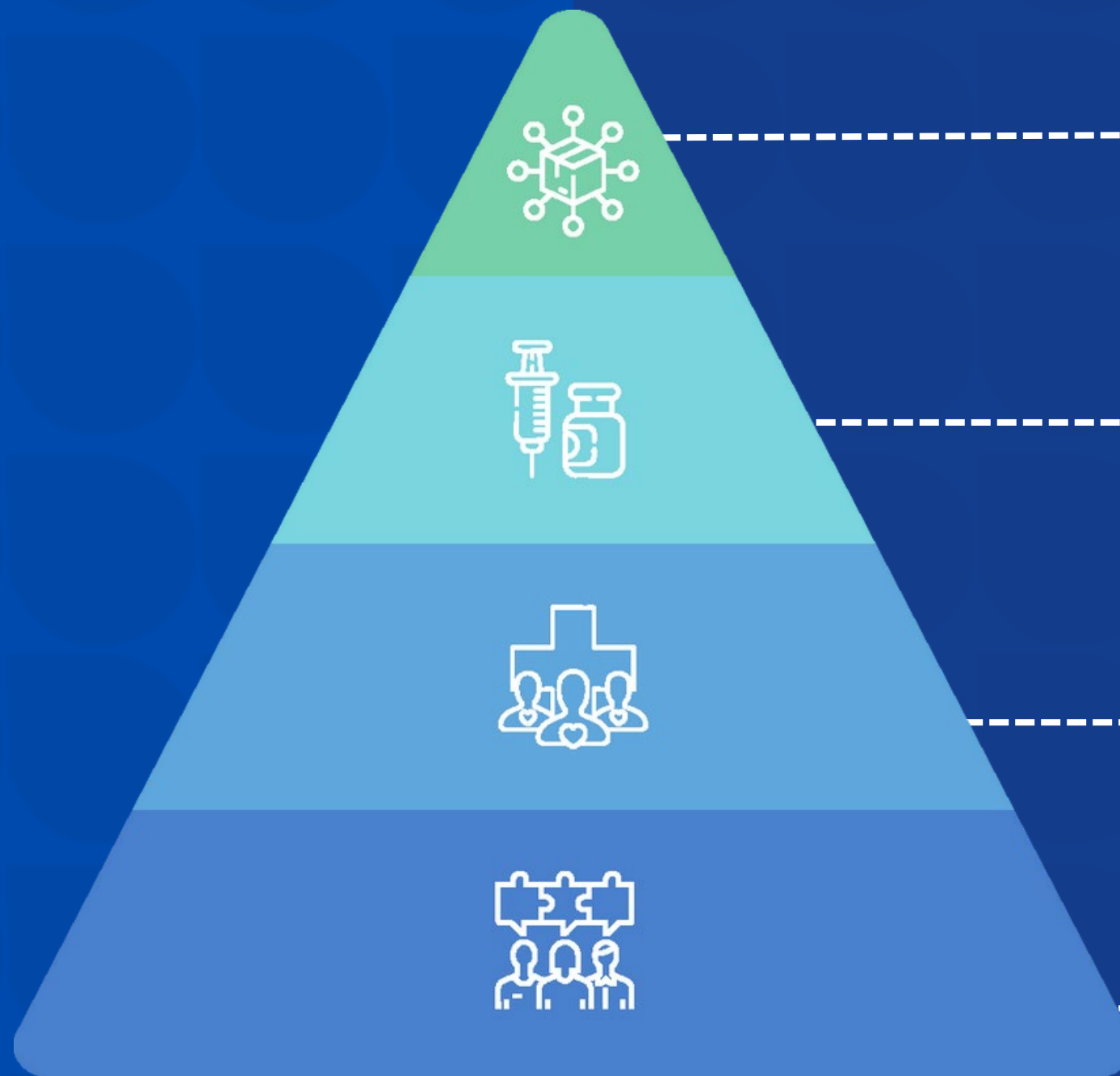
Bio-Manguinhos

Since 1976, Fiocruz has led vaccine production, development, and innovation in Brazil.

As one of the country's largest public laboratories, it delivers a wide range of vaccines supplied by the National Immunization Program to the population.

Commitment to public health and national sovereignty.





Supply 2021 – 2025

- Over 660 million vaccine doses supplied to the National Immunization Program (PNI) and UN Agencies
- Almost 130 million diagnostic test reactions
- Over 40 million biopharmaceutical units

More than 50 products in the portfolio

- 9 vaccines
- 34 diagnostic kits
- 10 biopharmaceuticals

Solutions for Public Health

- From routine to emergencies
- From national to global

More than 2,200 workers



Portfolio

From Prevention to Treatment



VACCINES

- Viral
- Bacterial

1



In Vitro Diagnostics

- Serological
- Molecular
- Parasitological
- Antigens

2



BIOPHARMACEUTICALS

- Monoclonal antibodies
- Recombinant proteins

3



ADVANCED THERAPIES

- CAR-T (cancer)
- Rare Diseases

4

Vaccines



More than 84 million doses delivered
to the National Immunization
Program (PNI) in 2025

- 🇧🇷 • Measles, mumps and rubella vaccine - 10 doses;
 - Measles, mumps, rubella and varicella vaccine - 1 dose;
- 🇺🇸 🇧🇷 • Yellow Fever – 5 and 10 doses;
 - Inactivated Polio 1, 2, and 3 – 10 doses;
- 10-valent pneumococcal – 1 and 4 doses;
- Meningococcal ACWY conjugate – 1 dose;
- Human rotavirus – 1 dose;
- 🇧🇷 • Measles and rubella (attenuated) – 10 doses;
- Hexavalent – 1 dose;



Exports



- **Yellow fever and Meningococcal AC/ACW*** vaccines;
- **More than 75 countries;**
- **Over the last 5 years, nearly 50 million doses of YF vaccine were exported;**
- **16,5 million doses exported to 18 countries in 2024.**

* In partnership with Finlay Institute

Diagnostic kits



More than 11,5 million reactions delivered to the Brazilian Ministry of Health in 2025

Covid-19

- POC Covid-19 Ag
- POC Triple

HIV/Syphilis

- HIV-1/2 rapid test
- HIV 1/2 self-test
- DPP® Rapid Immunoblot-HIV-1/2
- DPP® HIV/Syphilis Combo
- POC Syphilis
- DPP® Syphilis Duo

Zika/Dengue Chikungunya

- DPP® ZDC IgM/IgG
- DPP® Zika IgM/IgG
- DPP® Dengue IgM/IgG
- POC DPP® Dengue NS1
- DPP® Chikungunya IgM/IgG

Leishmaniasis Canine/Human

- DPP® Canine Visceral Leishmaniasis
- EIE Visceral Canine Leishmaniasis
- POC Human Visceral Leishmaniasis

Chagas/Leptospirosis/Malaria/Schistosomiasis

- TR Chagas
- IFI Chagas
- POC Malaria falciparum/vivax
- POC Malaria Pf/Pan
- POC Hantavirus
- Helm Test

Molecular Diagnostic Kits



HIV, Hepatitis B, C and Malaria

**NAT Plus Kit
(HIV/HCV/HBV/Malaria)**
Detects HIV, Hepatitis B,
Hepatitis C and Malaria

Respiratory Virus

VS/VR Molecular Kit
Detects measles and rubella
**Respiratory Viruses Panel
Molecular Kit**

COVID-19, Influenza (A/B) and variants

**Molecular Kit 4Plex
SC2/VOC**
Identifies COVID-19 and its
variants

Arboviruses

ZC Molecular Kit – D Typing
Detects Zika, Chikungunya
and 4 Dengue serotypes
Mayv/Orov Molecular Kit
Detects Zika, Chikungunya
and 4 Dengue serotypes

Yellow Fever

**Yellow Fever Molecular
Kit**
Specific diagnosis of Yellow
Fever
**Discriminatory Yellow
Fever Kit**
Confirms yellow fever
infection by differentiating it
from other viruses

Monkeypox and other viral infections

**Monkeypox Molecular Kit
(MPXV)**
Monkeypox Specific
Diagnosis
**Molecular Multiplex Kit
(OPV/MPXV/VZV/RP)**
Detects multiple viral
diseases in a single test

Biopharmaceuticals



More than 15,8 million vials, syringes and cartridges supplied to the Brazilian Unified Health System (SUS), ensuring access and strengthening public health.

*Under registration

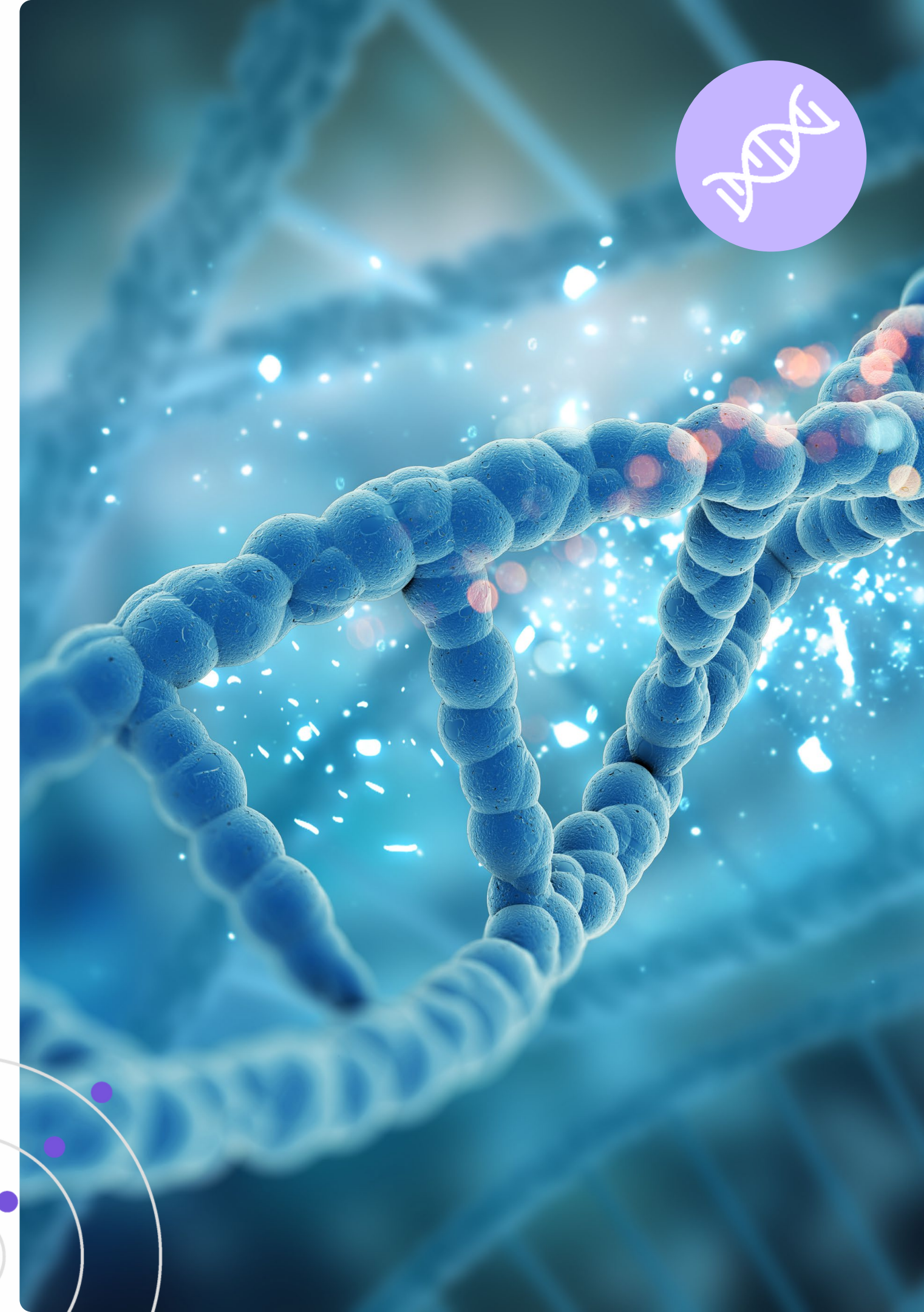
- **Adalimumab** – Indicated for the treatment of rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, among other conditions
- **Alfataliglicerase** – Indicated for the treatment of Gaucher disease
- **Epoetin alfa** – Indicated for anemia associated with chronic kidney disease
- **Infliximab** – Indicated for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, Crohn's disease, ulcerative colitis and psoriasis
- **Beta-Interferon (1a)** – multiple sclerosis
- **Etanercept** – Indicated for rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, and psoriasis
- **Somatropin 4 IU and 12 IU** – Indicated for hypopituitarism and Turner syndrome
- **Rituximab** – Indicated for non-Hodgkin lymphoma, follicular lymphoma, and rheumatoid arthritis
- **Trastuzumab** – Indicated for HER2-positive breast cancer
- **Golimumab** – Indicated for rheumatoid arthritis, ankylosing spondylitis, and psoriatic arthritis
- **Insuline Glargine*** – Diabetes (2025)
- **Nusinersene*** – SMA – Spinal Muscular Atrophy



Advanced Therapies

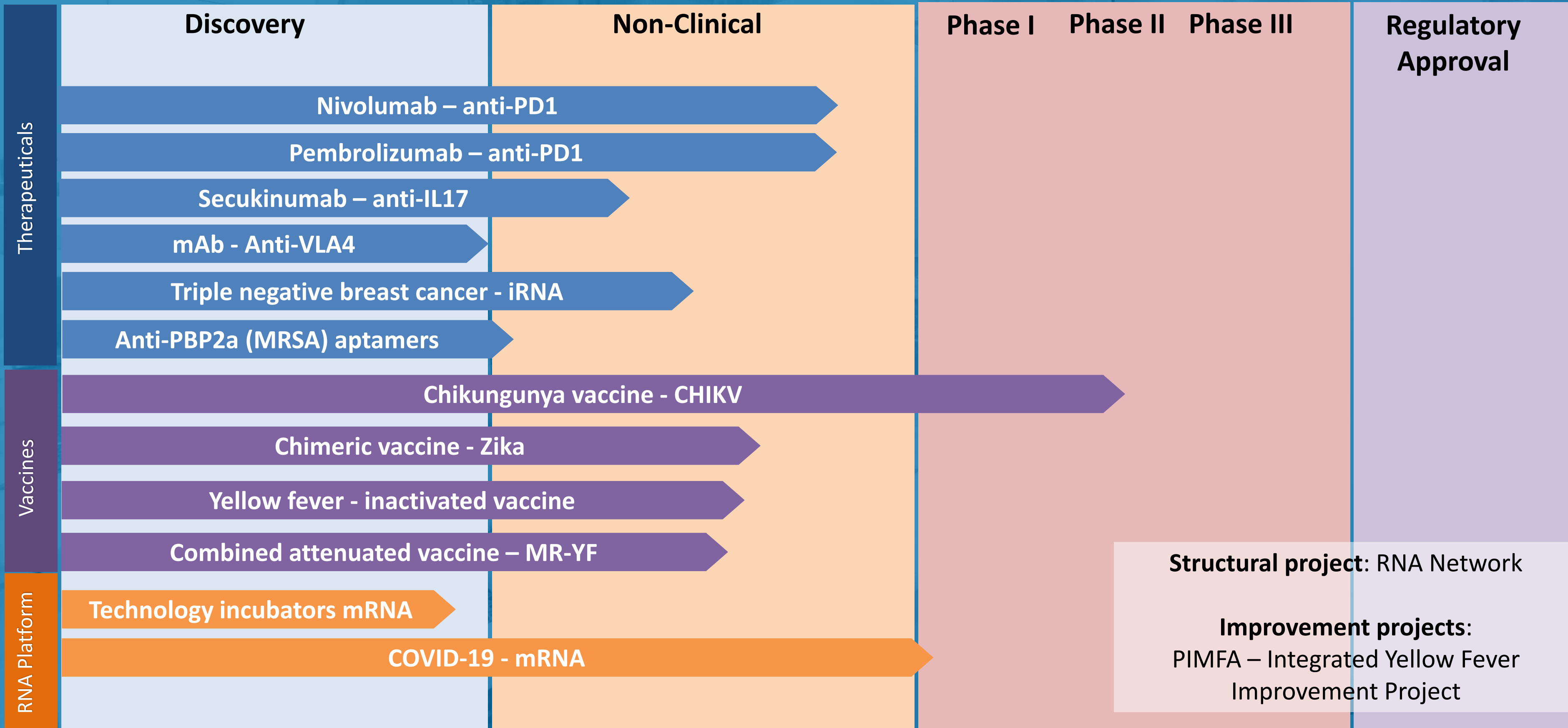
Innovation to expand the population's access to cutting-edge treatments

- **Regional leadership:** the only institution with mastery of this technology in Brazil and Latin America
- **Strategic projects:** CAR-T for cancer and pioneering therapies for rare diseases
- **Excellence in partnerships:** collaboration with Caring Cross and INCA in cutting-edge clinical trials
- **Impact on the Brazilian Unified Health System (SUS):** treatments up to 90% more affordable compared to the US and Europe
- **Social commitment:** free and universal access guaranteed through SUS



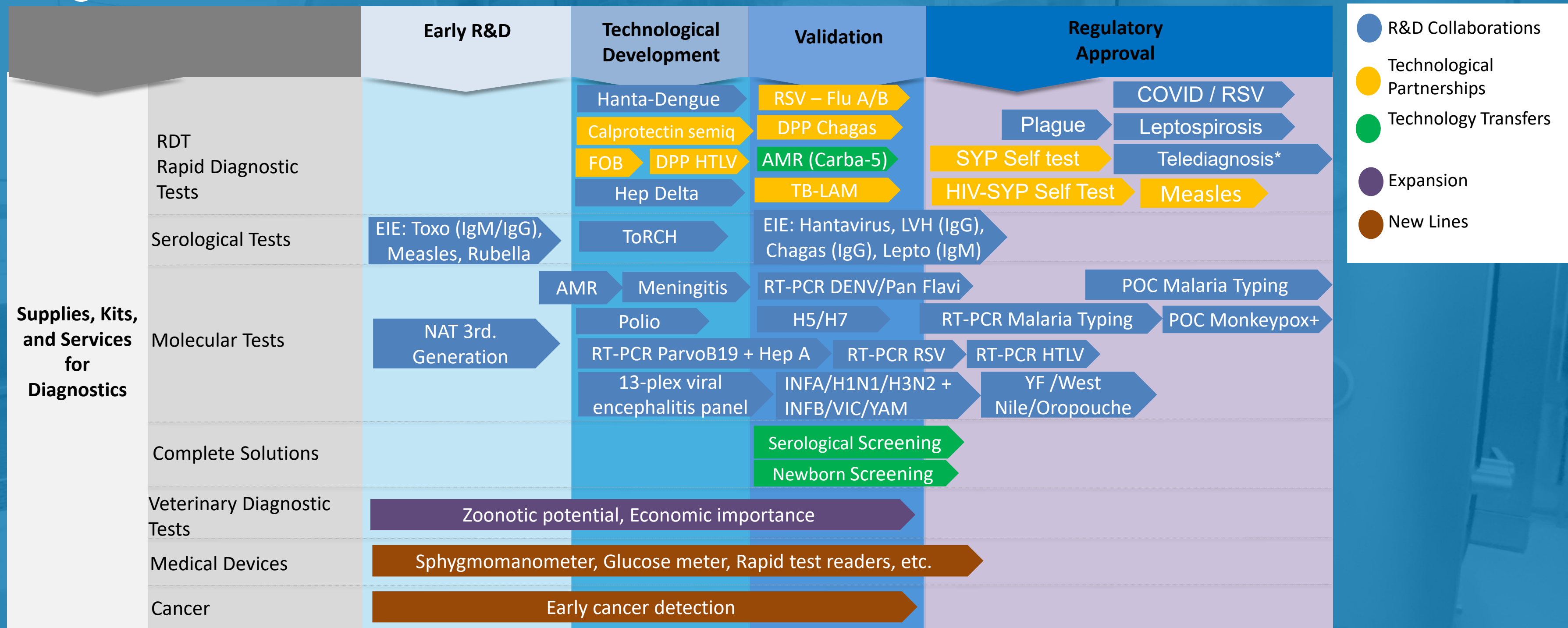
R&D Pipeline

Vaccines & Biopharmaceuticals



R&D Pipeline

Diagnostic Kits



*Dengue IgG/IgM and NS1, HBsAg, Influenza A/B, Zika IgG/IgM, HIV, Syphilis, Anti-HCV; Complete Blood Count, Beta-HCG, Renal Function, Blood Glucose, Glycated Hemoglobin, C-Reactive Protein, Lipid Profile, PSA, Vitamin D, Calcium, Potassium, Sodium, AST/ALT.

FOB (Fecal Occult Blood Test); AMR = antimicrobial resistance; ToRCH = Toxoplasmosis, Rubella, Cytomegalovirus, Herpes Simplex, Syphilis, and HIV; POC = point-of-care; YF = Yellow Fever.



Technology Transfer

Full incorporation of technology::

- 15 Technology Transfer Projects
- Self-sufficiency in national production
- Sustainable technological development
- Cost-effectiveness
- Strengthening the Health Economic and Industrial Complex

Fast Impact:

- Driving expanded access
- Ensuring greater agility in delivery





Productive Development Partnerships (PDP) and Technology Transfer (TT)

National self-sufficiency & Expanded access



Vaccines

- MMRV | **PDP** | GSK
- Rotavirus | **TT** | GSK
- ACWY | **TT** | GSK
- Polio (IPV) | **TT** | Sanofi
- Hexavalent | **TT** | Sanofi



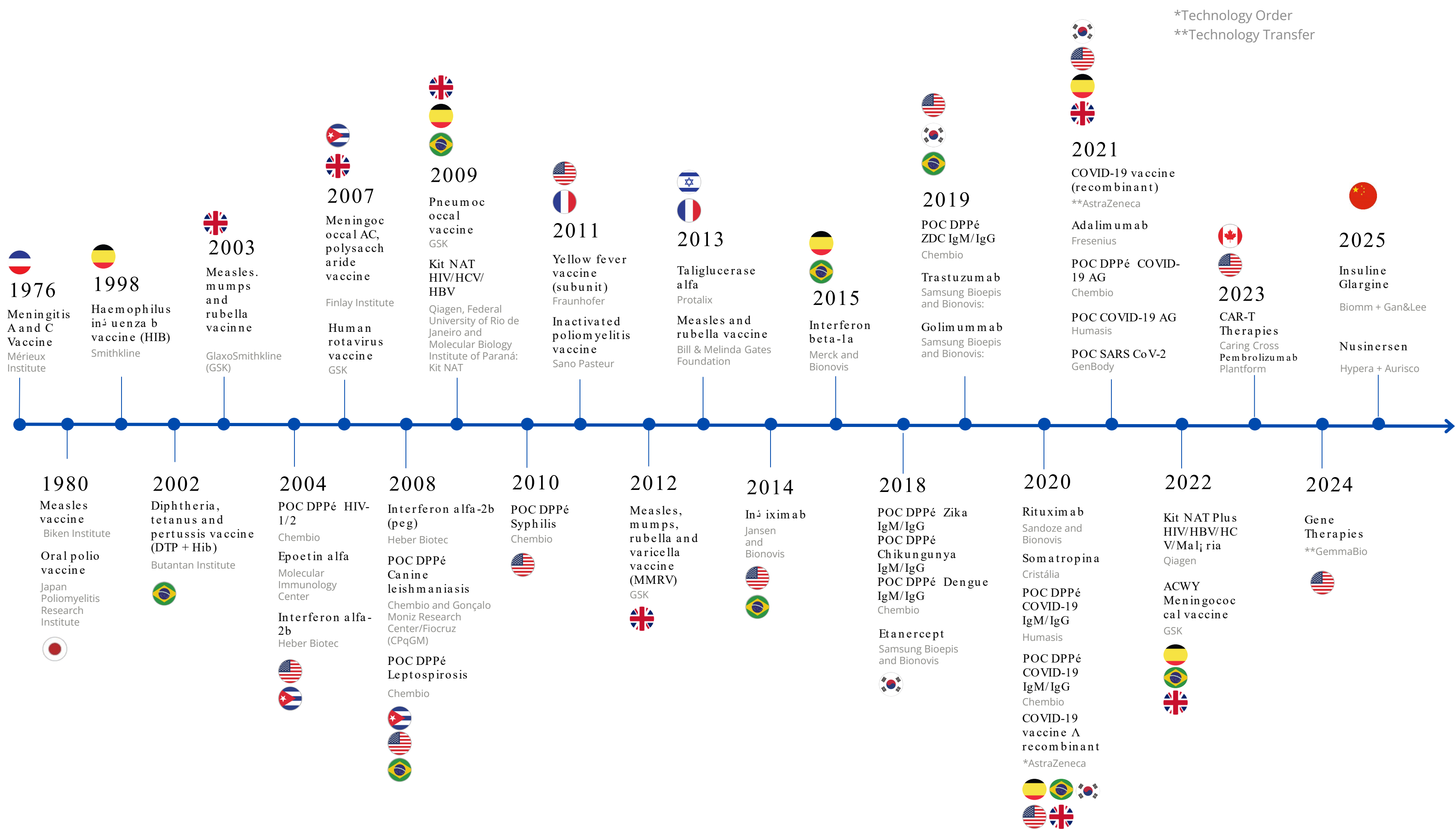
Biopharmaceuticals

- Epoetin Alfa | **TT** | Ciamab (CIM)
- BETA - Interferon 1a | **PDP** | Merck Serono
- Infliximab | **PDP** | Janssen-Cilag
- Golimumab | **PDP** | Janssen-Cilag
- Etanercept | **PDP** | Samsung Bioepis
- Trastuzumab | **PDP** | Samsung Bioepis
- Rituximab | **PDP** | Sandoz
- Adalimumab | **PDP** | Fresenius-Kabi



Advanced Therapies

- **TT** | Caring Cross
- **TT** | Gemma



Empowering Brazil's Health Industrial Complex

The Future of National Sovereignty in Immunobiologicals

➤ Industrial Complexes and Platforms

- Biotechnology Industrial Complex for Health (Santa Cruz – RJ)
- Technological Complex for Strategic Inputs (Bio-Ceará)
- Technological Center for Diagnostics (former Biomérieux | Jacarepaguá)

➤ Installed and Ongoing Capabilities

- mRNA Platform
- Expansion of the API manufacturing plant for viral vaccines
- Modernization of the API manufacturing plant for bacterial vaccines
- Modernization of the Industrial Park for Diagnostic Reagents



mRNA Vaccine

Project selected by PAHO/WHO – R&D Center and Technology Transfer

Cutting-edge technology: formulation with lipid nanoparticles, ensuring greater stability and efficiency.

Scientific advancement: pre-clinical study already accomplished with excellent results and toxicological study completed.

Next steps: preparing for the manufacturing of clinical batches, highlighting a decisive step towards the next phase of development.



RSV – Leishmaniasis – Oropouche Fever – Smallpox –
Tuberculosis – Yellow Fever – Zika – Monoclonal
Antibodies – Therapeutic Vaccines



Technological Complex in Strategic Inputs (Bio-Ceará)

Next-Generation Biomanufacturing of Active Pharmaceutical Ingredients (APIs)

Treatment for:

- Diabetes
- Cancer
- Chronic diseases
- Inflammatory diseases (such as rheumatoid arthritis and Crohn's disease)
- Turner Syndrome and Hypopituitarism

- Land area: 225,000 m²
- Built area: 77,000 m²
- Number of buildings: 24
- Jobs (operation): ~400
- Investment: ~R\$ 1 billion



04AB



Development and Innovation Diagnostics Center

**BioMérieux & Fiocruz new production site
(Jacarepaguá – RJ)***

Facility dedicated to diagnostic innovation

- Around 40,000 m² of built area
- Transfer of the entire production line
- Final processing/product assembly
- Quality control
- New area dedicated to stability testing for quality control of all portfolio kits
- Storage area

Positive Impacts:

- Technological upgrading
- Expansion of production capacity in diagnostic testing
- Automation of production processes
- Reduction of production time



Thank You!

business.development@bio.fiocruz.br



MINISTÉRIO DA
SAÚDE

