

Mediterranean  
Thematic Workshops  
in Advanced Molecular Imaging

# AVAILABILITY AND AFFORDABILITY OF PET IN BRAZIL: CHALLENGES AND OPPORTUNITIES

Ana Maria Marques Da Silva, Prof. Dr.

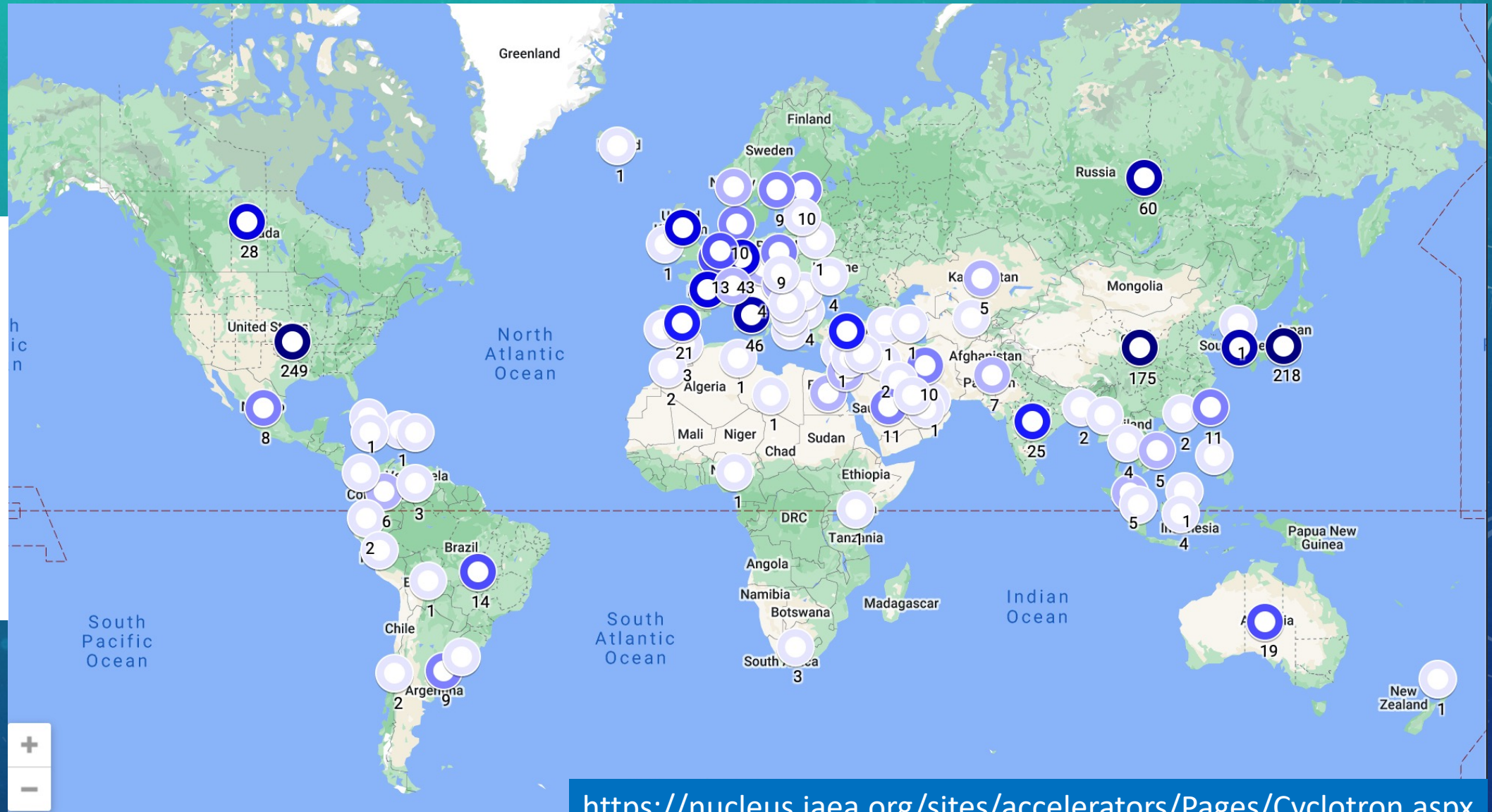
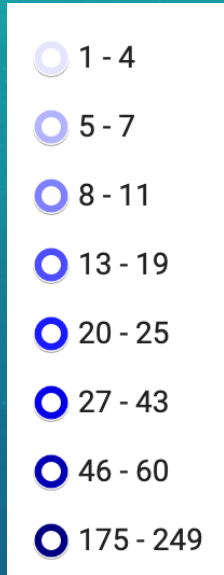
Medical Imaging & Data Analytics

Brazil/USA

# INTRODUCTION

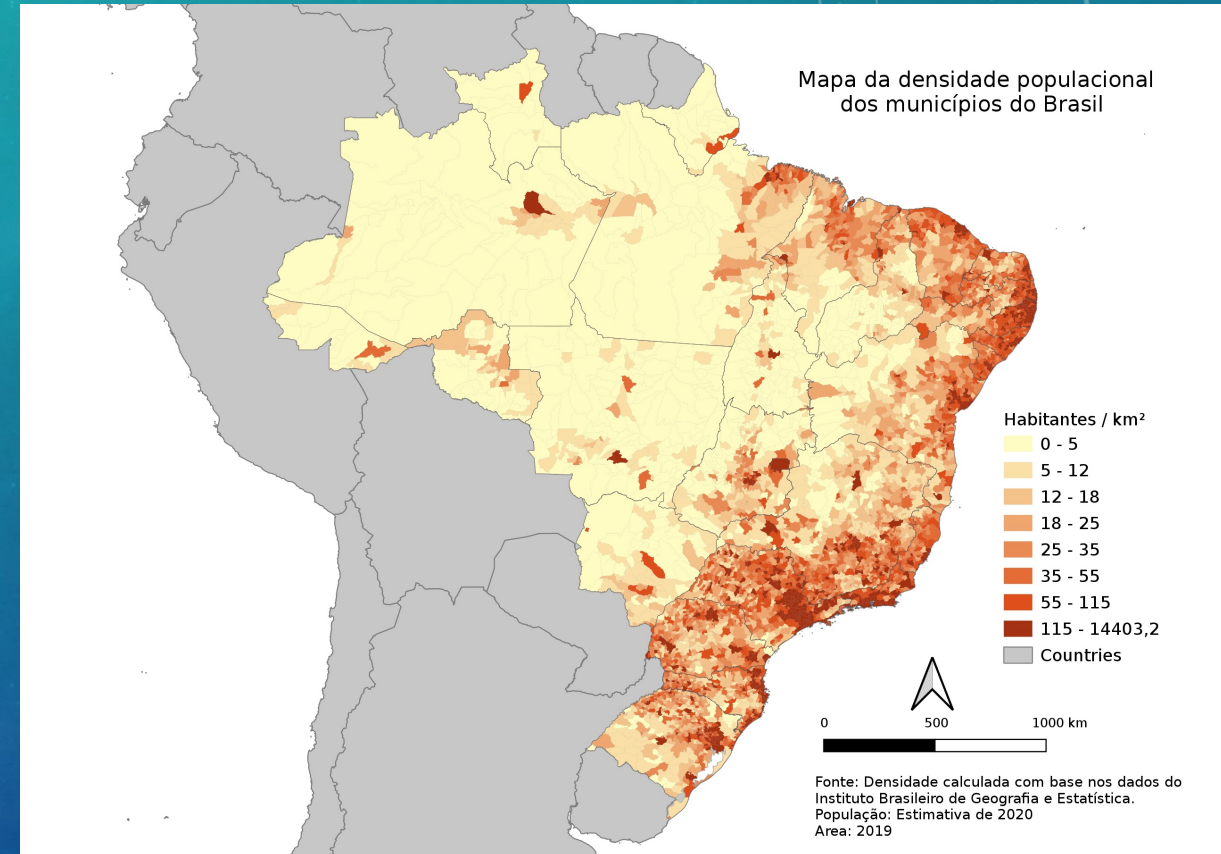
- PET technology was developed in the late 1970s.
- PET is a proven useful tool for the diagnosis and management of oncological, neurological, and cardiological disorders.
- It became more feasible in clinical settings only during the 1990s, thanks to the technology developments and commercialization of compact cyclotrons, which are now widely available.
- The Database of Cyclotrons for Radionuclide Production (IAEA, 2022) shows around 1,300 cyclotron facilities for medical production around the world.

# INTRODUCTION



# INTRODUCTION

- Brazil is the largest Latin American country, occupying an area of 8,511,965 km<sup>2</sup>.
- It covers nearly half of the South American landmass.
- It is the fifth largest country in the world after the Russian Federation, Canada, China and the United States.
- It 2019, it had about 210 million inhabitants, unequally distributed in the country.

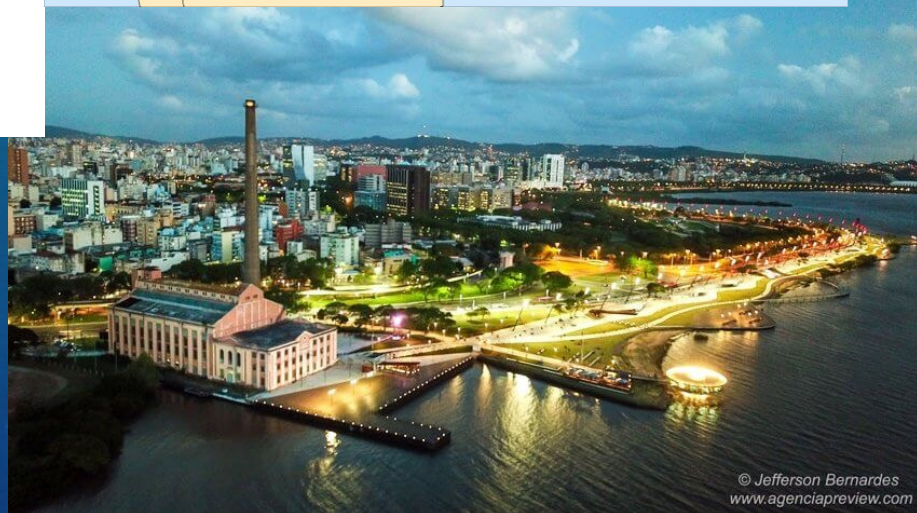


# MY CITY

## Porto Alegre, Brazil



- Foundation: 1772
- Population: 1.5 million inhabitants
- Metropolitan Area: 4.0 M inhabitants
- 19<sup>th</sup> century European immigrants (Portugal, Italy, Germany, Spain) and native indians groups.



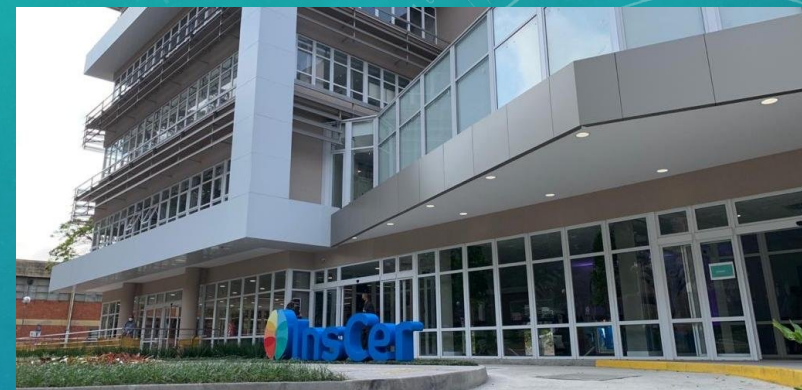
# MY INSTITUTION

## InsCer – Brain Institute

<http://inscer.pucrs.br/>



Since 2012



### Radiopharmaceuticals Production Center



### Imaging Center



### Preclinical Research Center

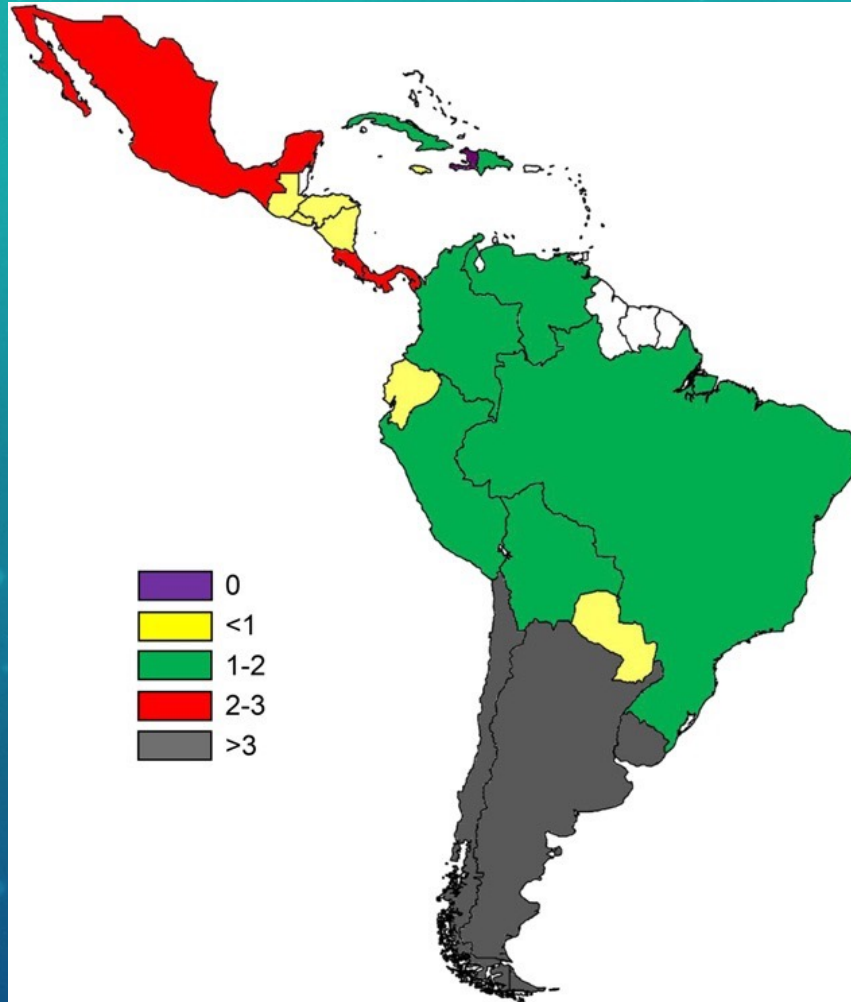


# GOAL

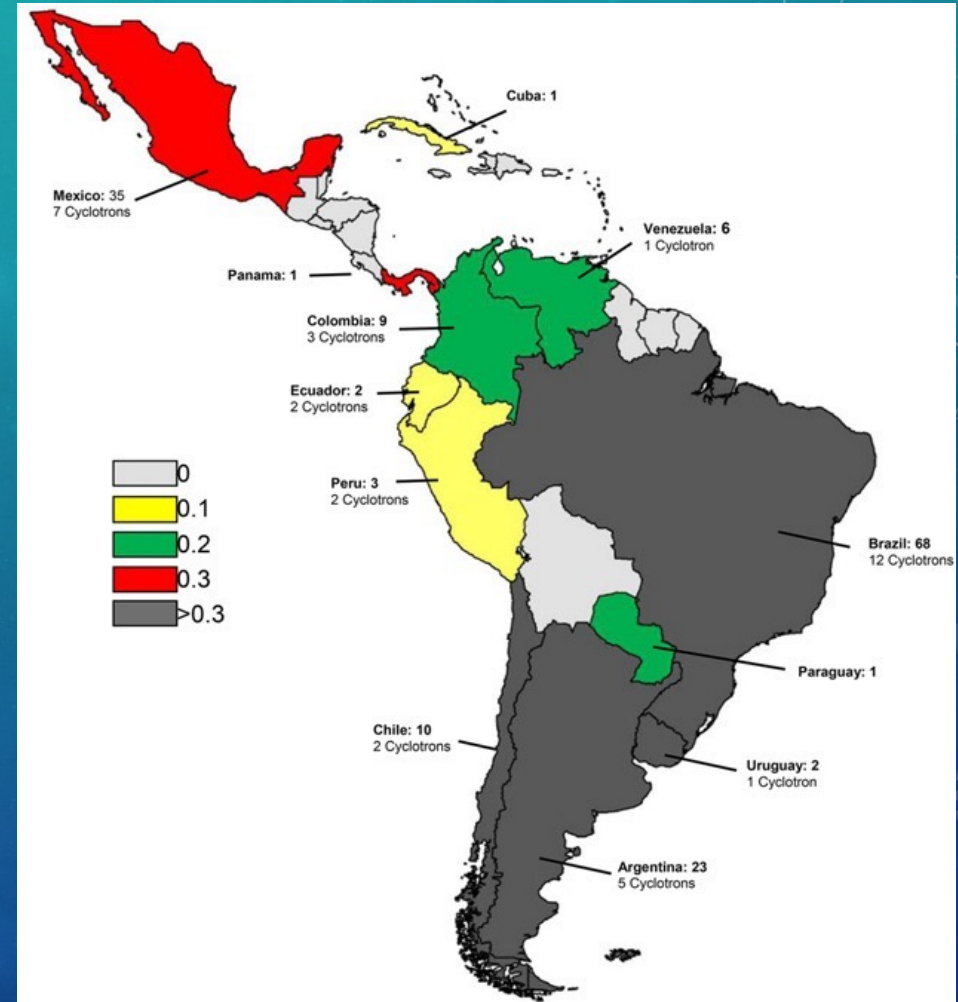
My goal is to provide a broad view about the availability and affordability of PET in Latin America, but especially in Brazil.



# INFRASTRUCTURE IN LATIN AMERICA



Number of gamma cameras per million population

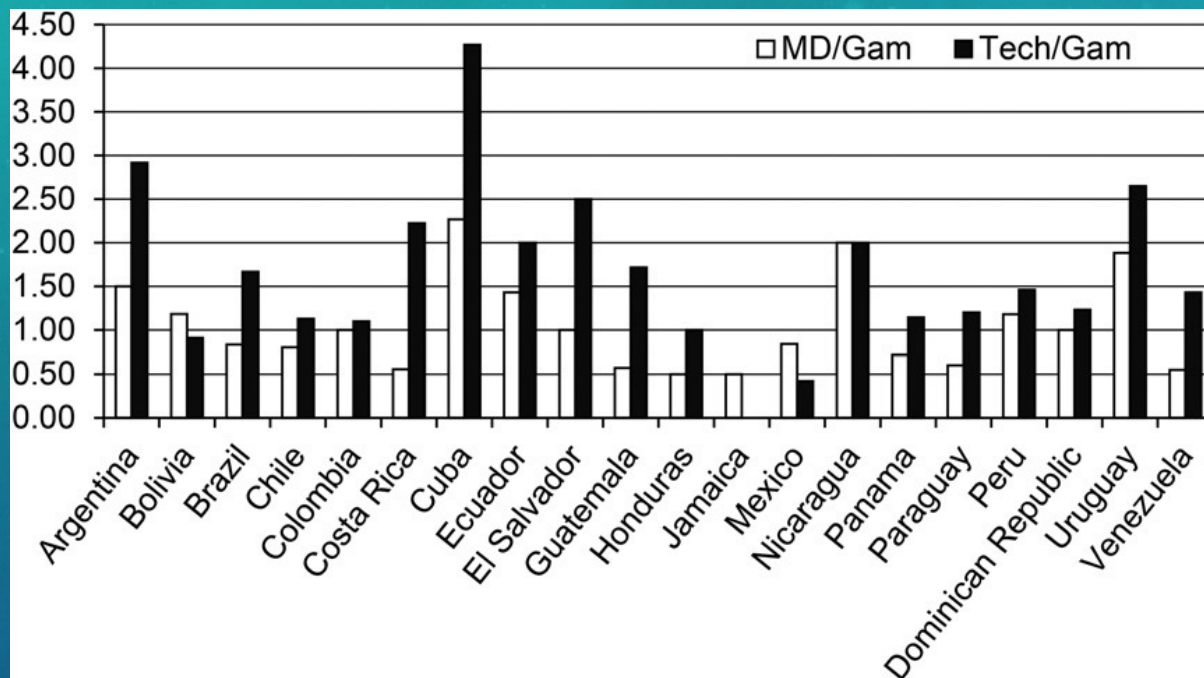


PET and PET/CT systems installed in the region.

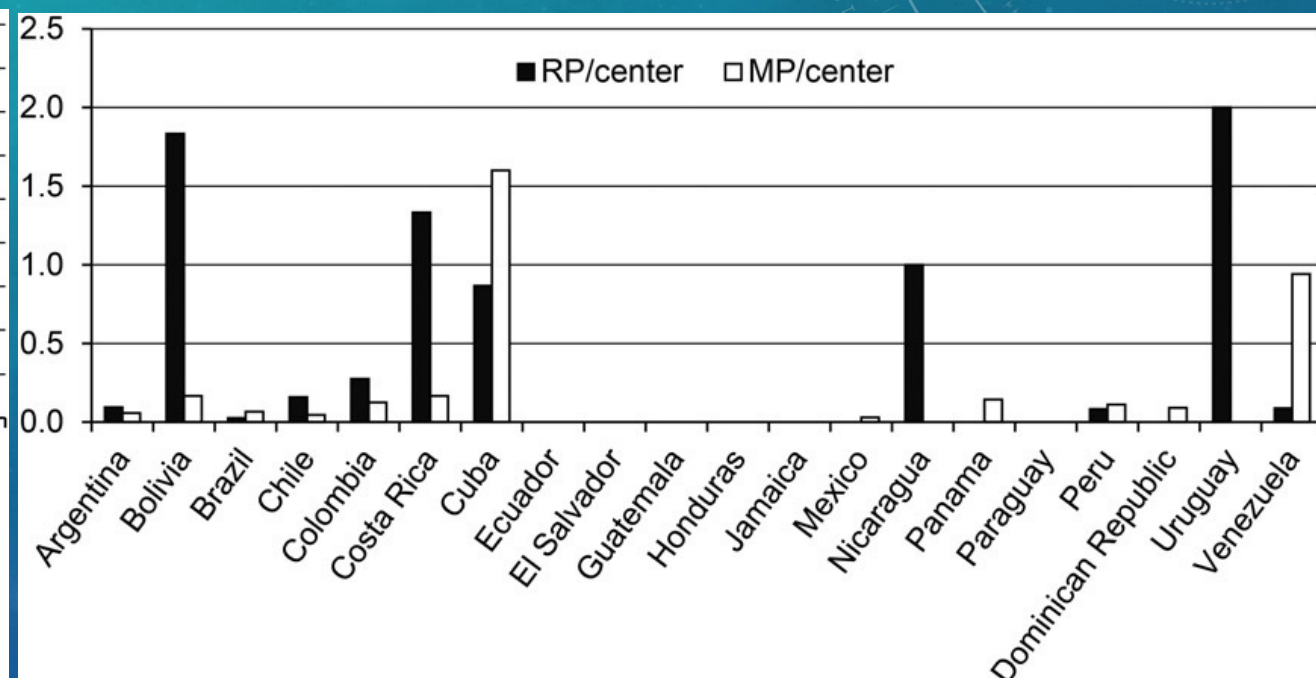


# HUMAN RESOURCES IN LATIN AMERICA

- Lack of human capacities in cyclotron operation, production, and QC of PET radiopharmaceuticals.



NM physicians (MD) and technologists (Tech) per gamma camera (Gam)



Nuclear physicists (MP) and radiopharmacists (RP) per center.

# INFRASTRUCTURE IN LATIN AMERICA

- First compact cyclotrons:
  - 1997 in Argentina
  - 2000 in Mexico
- IAEA assisted the member states (ARCAL\*) for capacity building/knowledge sharing:
  - Training courses, workshops, technical meetings
  - Expert missions
  - Fellowships and hands-on training
- 2010 – 15 cyclotrons
- Until July 2021 - 67 cyclotrons



**Table 1** Number of cyclotrons by country and estimated population

Country	Estimated population 2021 (millions)*	Number of cyclotrons	Density of cyclotrons**
Argentina	45.2	10	0.22
Bolivia	11.7	2	0.17
Brazil	212.5	16	0.08
Chile	19.1	3	0.16
Colombia	50.9	6	0.12
Costa Rica	5.1	1	0.20
Cuba	11.3	1	0.09
Dominican Republic	10.8	2	0.19
Ecuador	17.6	3	0.17
Jamaica	3.0	1	0.33
Mexico	128.9	10	0.08
Panama	4.3	1	0.23
Paraguay	7.1	1	0.14
Peru	33.0	2	0.06
Puerto Rico***	2.9	2	0.69
Trinidad y Tobago	1.4	1	0.71
Uruguay	3.5	2	0.57
Venezuela	28.4	3	0.11

\* <https://www.worldometers.info/population>, \*\*Per million population, \*\*\*Officially an unincorporated territory of the USA

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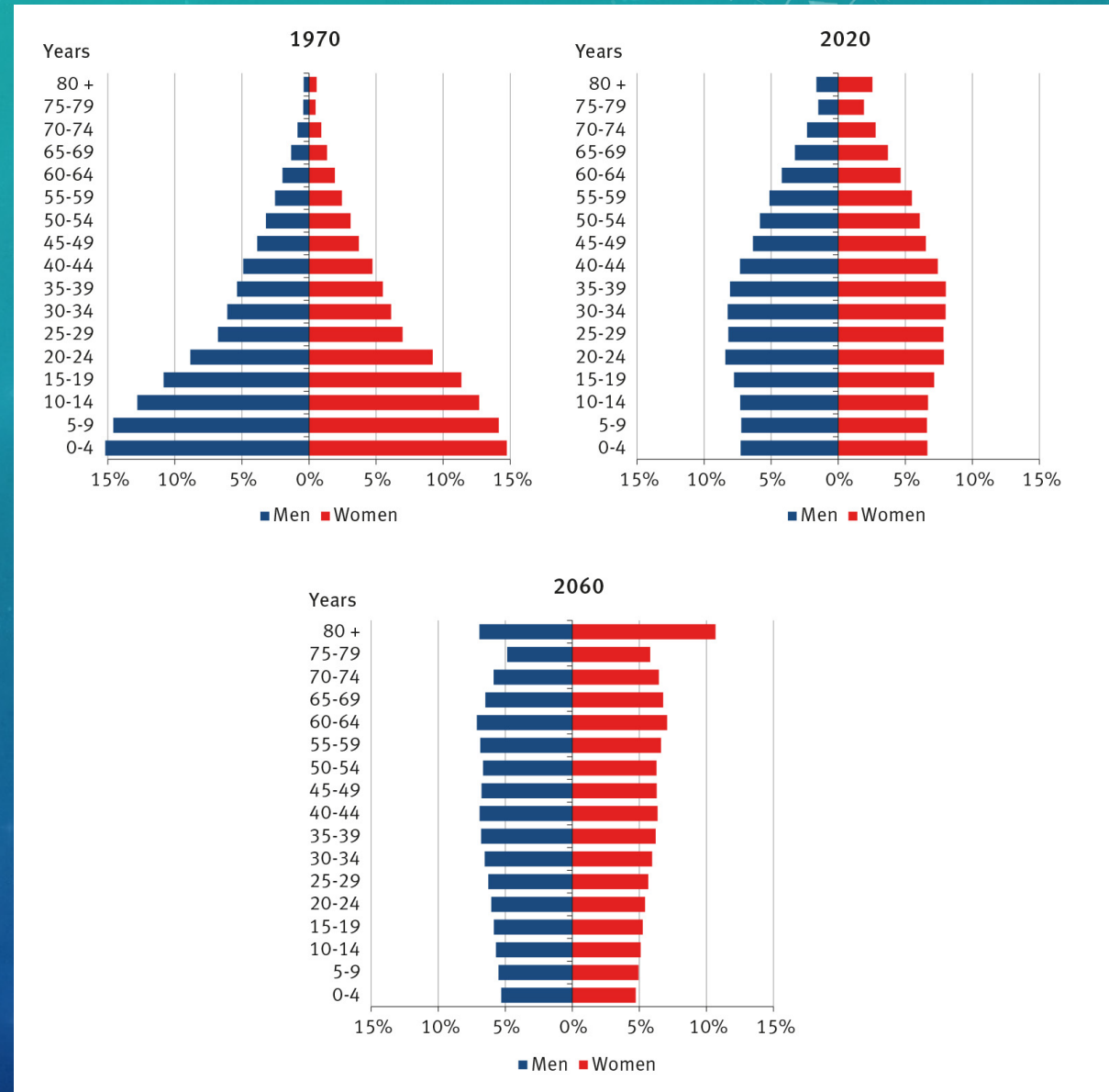
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**WHAT DO YOU  
NEED TO  
KNOW ABOUT  
BRAZIL?**

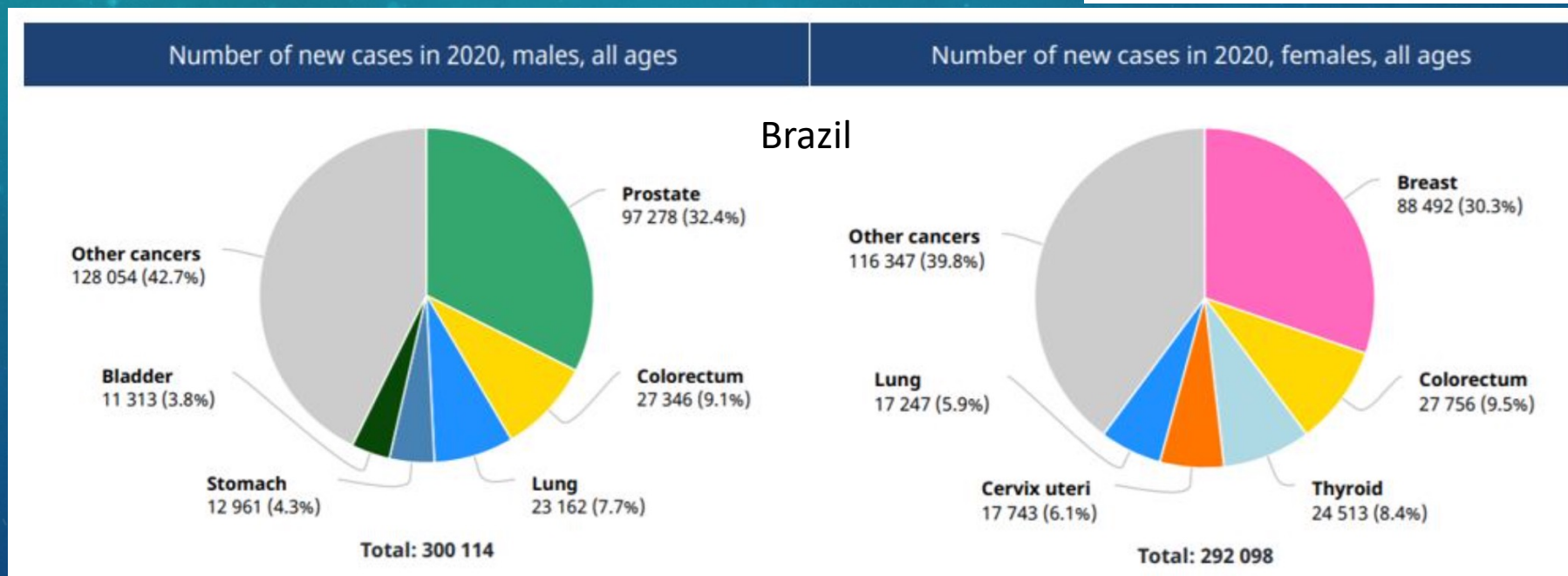
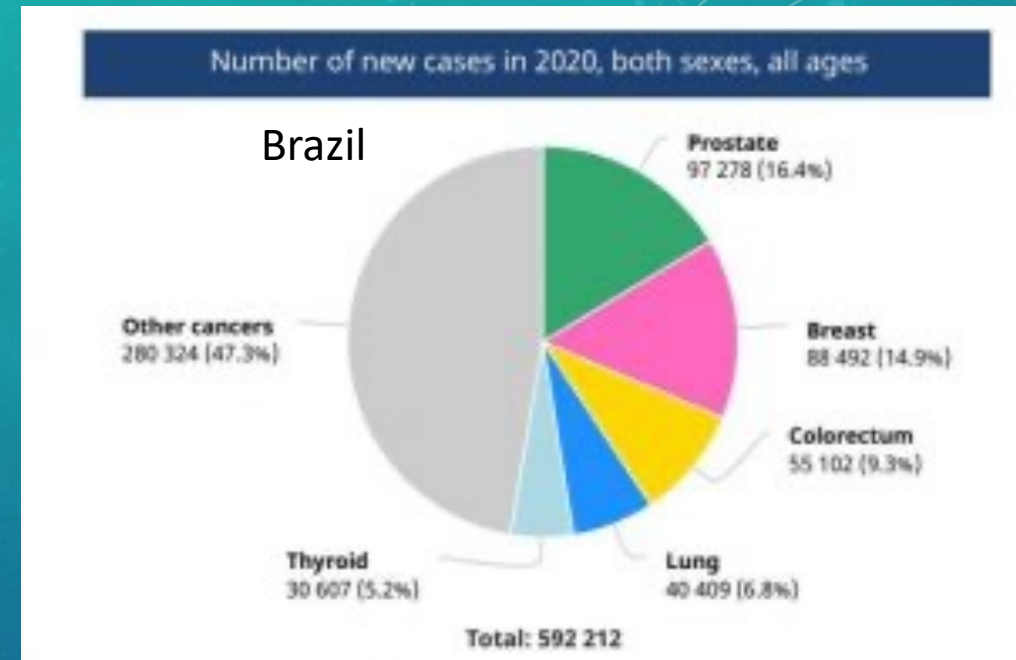
# DEMOGRAPHY IN BRAZIL

- There is a dramatic rise in the elderly population in Brazil.
- Due to social inequalities and the corresponding differences in total fertility rates, the poorest population has grown most, with strong consequences for changes in the age structure.
- The major aspects fueling the growth of diagnostic imaging in Brazil are:
  - Growing geriatric population
  - Increasing prevalence of chronic diseases
  - Increasing in funds by government bodies



# CANCER IN BRAZIL

- In Brazil, cancer is the second most common cause of death, after cardiac and cerebrovascular diseases.
- Oncology accounts for more than 30%.



# HEALTHCARE SYSTEM IN BRAZIL

- Health care in Brazil has a decentralized, universal public health system, funded with tax revenues and contributions from federal, state, and municipal governments, called Unified Health System (Sistema Único de Saúde - SUS).

## PUBLIC HEALTH (SUS)



### Funding

SUS is funded by federal, state, and municipal governments



### Health outcomes

Since the system's implementation, Brazil has experienced an increase in life expectancy and a reduction in infectious diseases, despite recent outbreaks



### Special Programs

The Programa Saúde da Família (PSF) provides primary care in low income areas through teams of healthcare professionals



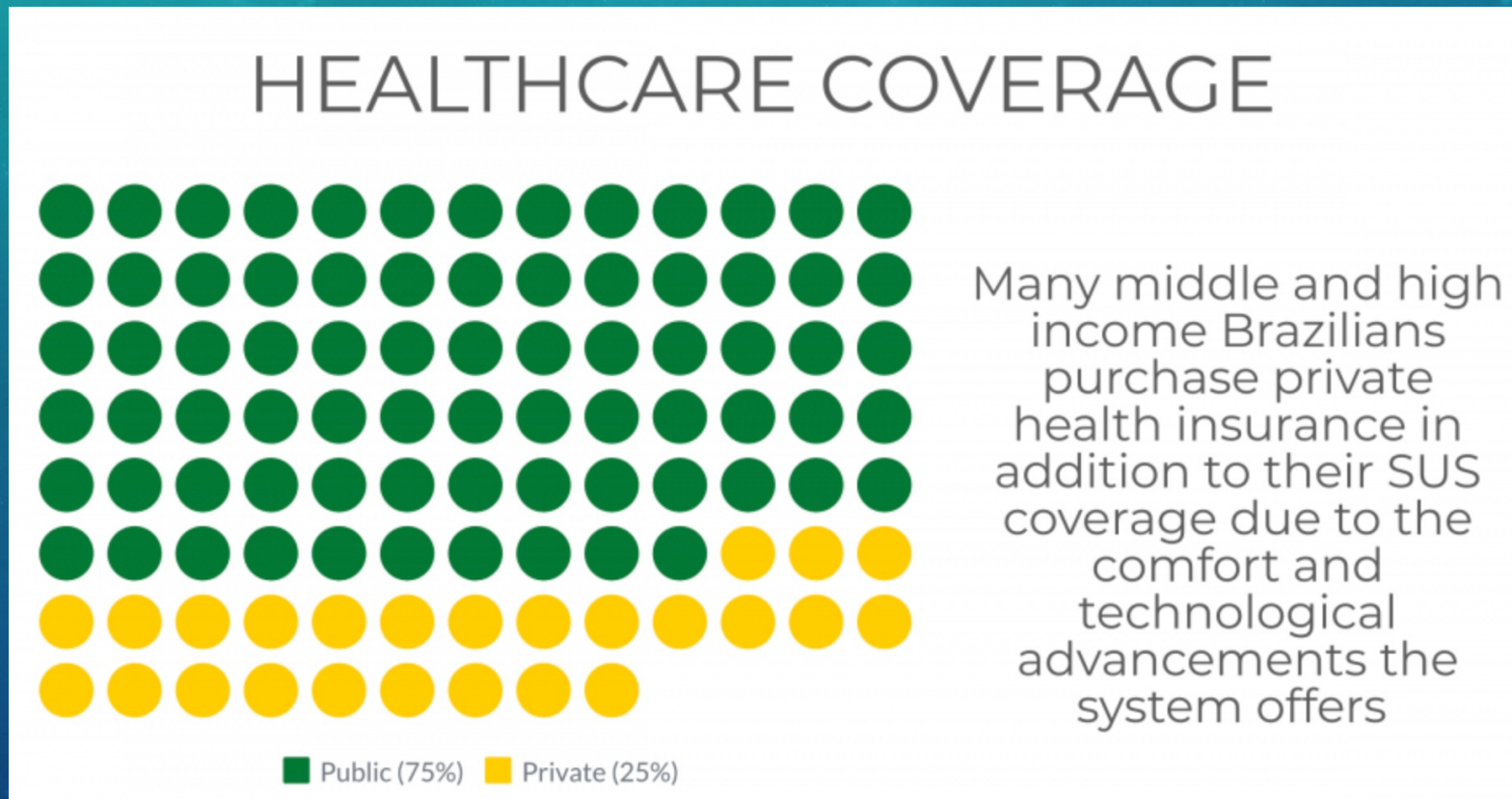
### Current Challenges

Low doctor/patient ratios in public healthcare facilities, high hospital wait times, and resource scarcity in public hospitals. These problems are exacerbated in poorer states



# HEALTHCARE SYSTEM IN BRAZIL

- There is an additional private health care system in Brazil.
- 75% of the population uses the public SUS services, but 25% has an additional private healthcare plan, usually funded by personal expenditures or by companies.



# HEALTHCARE SYSTEM IN BRAZIL

## PRIVATE HEALTH

50 million

Brazilians are covered  
by private plans



Brazil is the second  
largest private health  
market in the world

57%

of health spending  
is private sector



### Funding

The private sector is financed by patient expenditures and partially by the government through tax breaks from privately insured individuals who use high cost services and receive complex procedures through SUS



### Spending

More than half of private sector spending comes from out of pocket payments for services in private hospitals



### Current Challenges

As private healthcare is based in hospitals, not primary care facilities, the private sector shifts to focus away from preventative care to the treatment of already sick patients. High costs of insurance also pose problems for some patients



### COVID-19

As the Covid-19 pandemic progresses, the government may temporarily nationalize private hospitals to account for shortages in public hospitals

Complex imaging examinations (PET/CT) are done in public and private hospitals.  
Only few PET procedures are reimbursed by the public system.

# PET REGULATION IN BRAZIL

- Until 2006, the production and selling of short half-life radioisotopes was monopoly of the Brazilian Nuclear Energy Commission (CNEN), a governmental institution.
- In 2006, a Constitutional Amendment revoked the state monopoly, allowing private cyclotrons.
- PET emitting radioisotope manufacturing facility in Brazil requires the applicable regulatory aspects:
  - Security and radiation protection (regulation modified in 2013 to include PET facilities)
  - Radiopharmaceutical licensing and manufacturing (created in 2011, with a guideline in 2013, and several modifications)
- Changes in licensing nuclear medicine departments, created in 1989, had modifications in 2013 to include PET QC procedures and in 2020 to define staff requirements.

## REQUISITOS DE SEGURANÇA E PROTEÇÃO RADIOLÓGICA PARA SERVIÇOS DE MEDICINA NUCLEAR

Portaria CNEN/DExl 01/89  
Resolução CNEN 10/96  
Resolução CNEN 159/13



## LICENCIAMENTO DE INSTALAÇÕES RADIATIVAS

Resolução CNEN 112/11  
Publicação: DOU 01.09.2011  
Resolução CNEN 166/14  
Publicação: DOU 29.04.2014  
Resolução CNEN 215/17  
Publicação: DOU 30.06.2017  
Resolução CNEN 251/19  
Publicação: DOU 13.11.2019  
Resolução CNEN 261/20  
Publicação: DOU 29.05.2020

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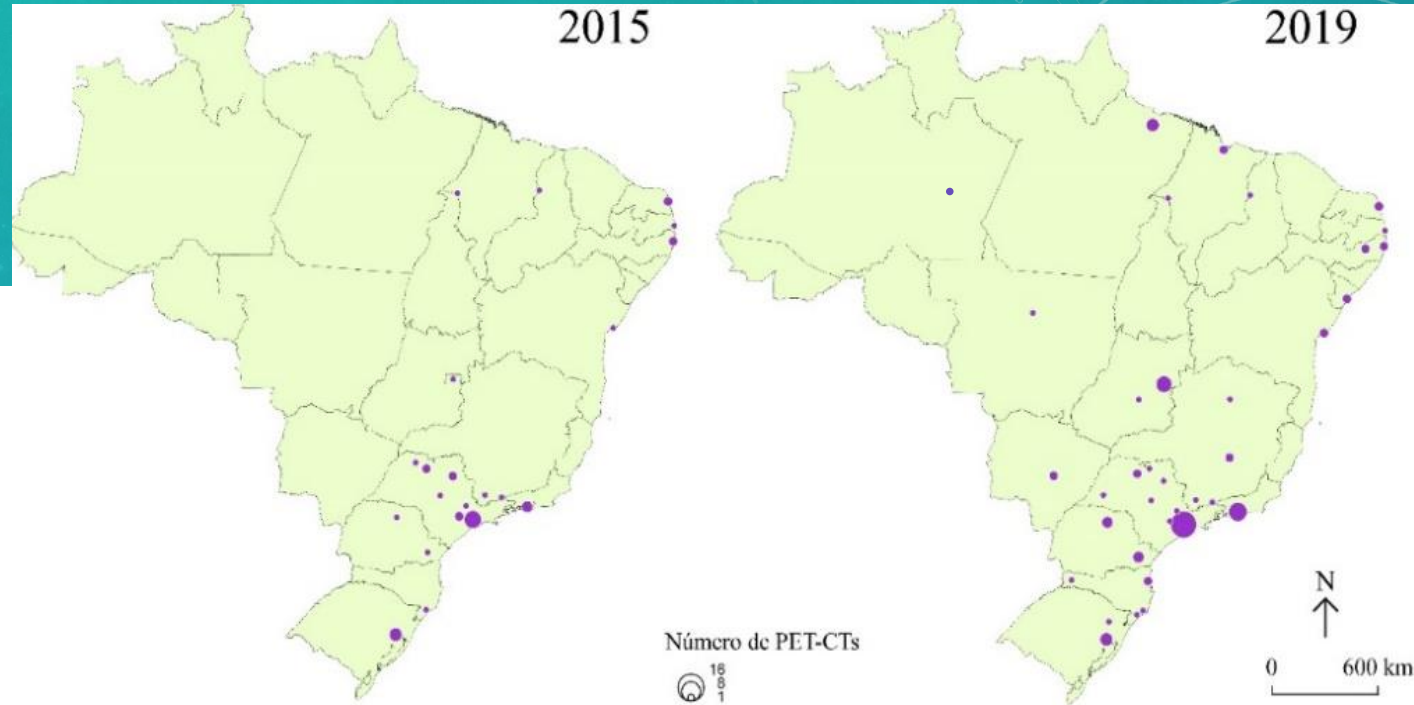
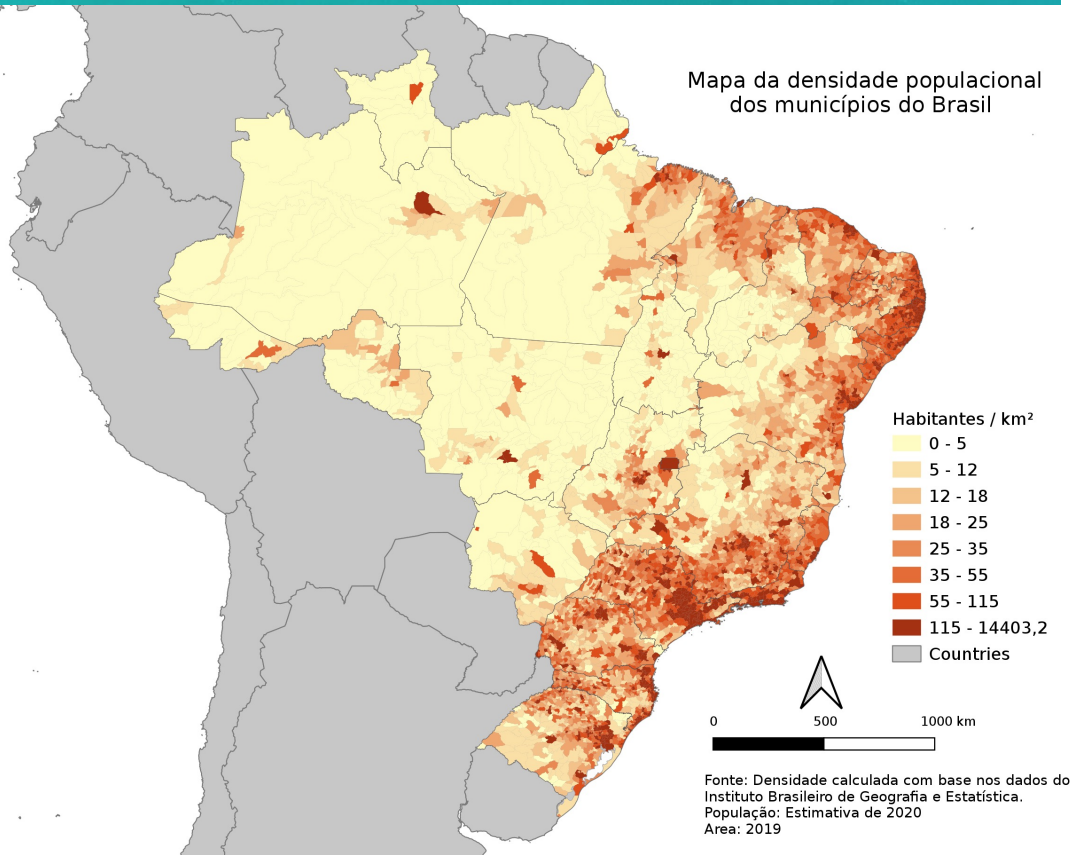


## CERTIFICAÇÃO DA QUALIFICAÇÃO DE SUPERVISORES DE PROTEÇÃO RADIOLÓGICA

Resolução CNEN 008/88 (Aprovação da Norma CNEN NE 3.03)  
Publicação: DOU 01.08.1988  
Resolução CNEN 005/95 (Aprovação da Norma CNEN NN 3.03)  
Publicação: DOU 01.09.1995  
Resolução CNEN 111/11 (revisão geral)  
Publicação: DOU 05.09.2011  
Resolução CNEN 146/13 (Alteração do inciso I do art. 13)  
Publicação: DOU 25.03.2013  
Resolução CNEN 194/16 (revisão geral)  
Publicação: DOU 01.06.2016  
Retificação: DOU 21.06.2016  
Resolução CNEN 259/20 (Alteração do §2º do art. 6º e do Parágrafo único do art. 9º)  
Publicação: DOU 02.03.2020

# INFRASTRUCTURE IN BRAZIL PET-CT

## Population Density (2020)

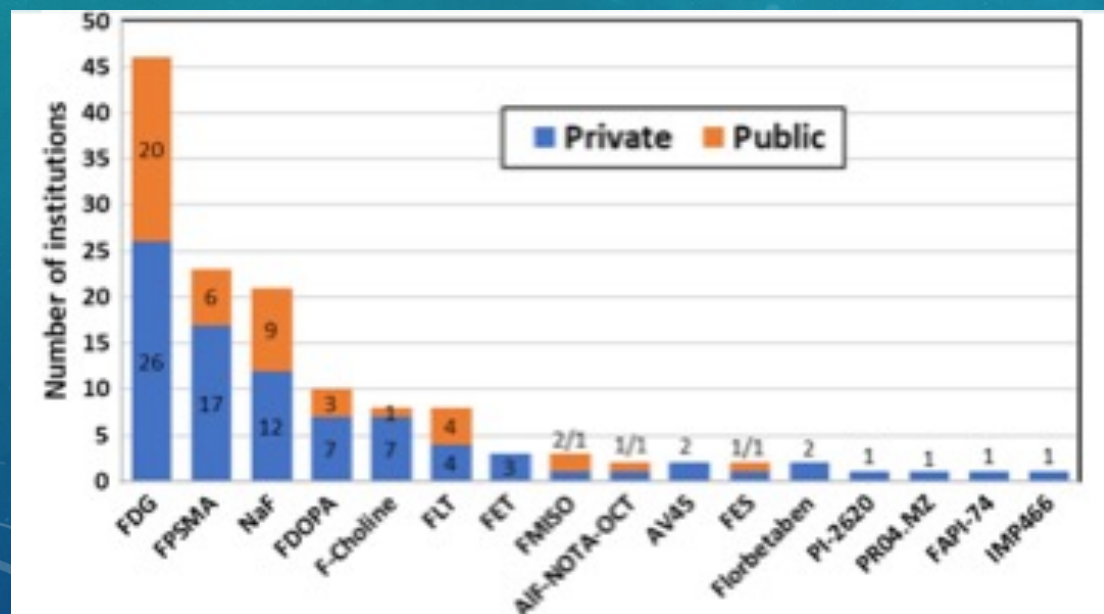


## Cyclotrons (2021) Training sites

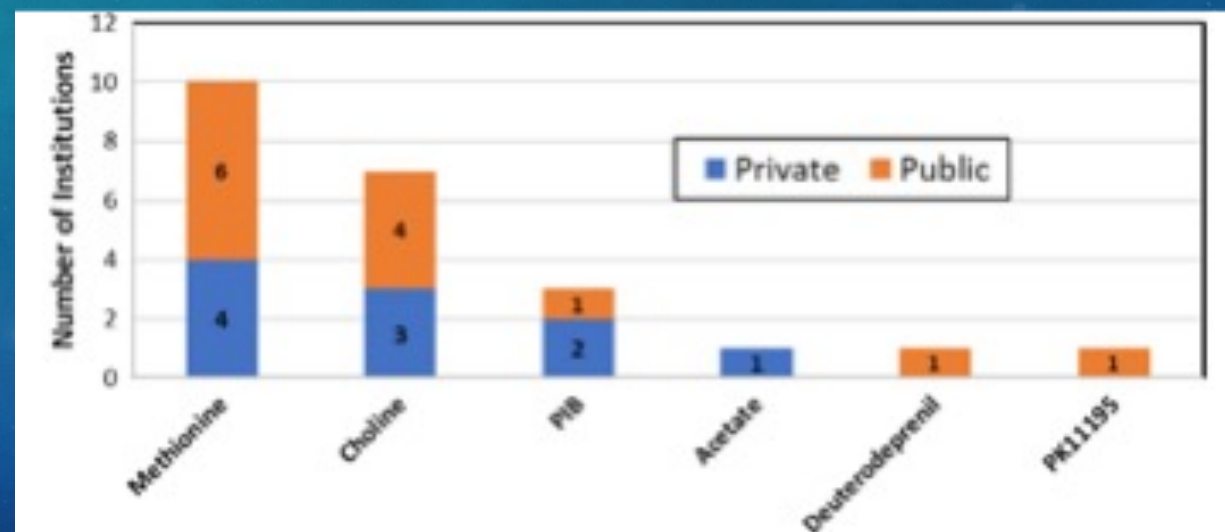


# PET TRACERS IN BRAZIL

- For clinical purposes, only  $^{18}\text{F}$ -FDG is reimbursed by Brazilian public and private healthcare systems for oncological investigations.
- However, other tracers are registered at ANVISA and authorized for clinical studies for cancer and neurodegenerative diseases, mainly with  $^{18}\text{F}$ -PSMA,  $\text{Na}^{18}\text{F}$ ,  $^{18}\text{F}$ -DOPA,  $^{18}\text{F}$ -Choline,  $^{18}\text{F}$ -FLT,  $^{11}\text{C}$ -Methionine,  $^{11}\text{C}$ -Choline and  $^{11}\text{C}$ -PIB.



Main F-18 radiopharmaceuticals produced in the LA region.



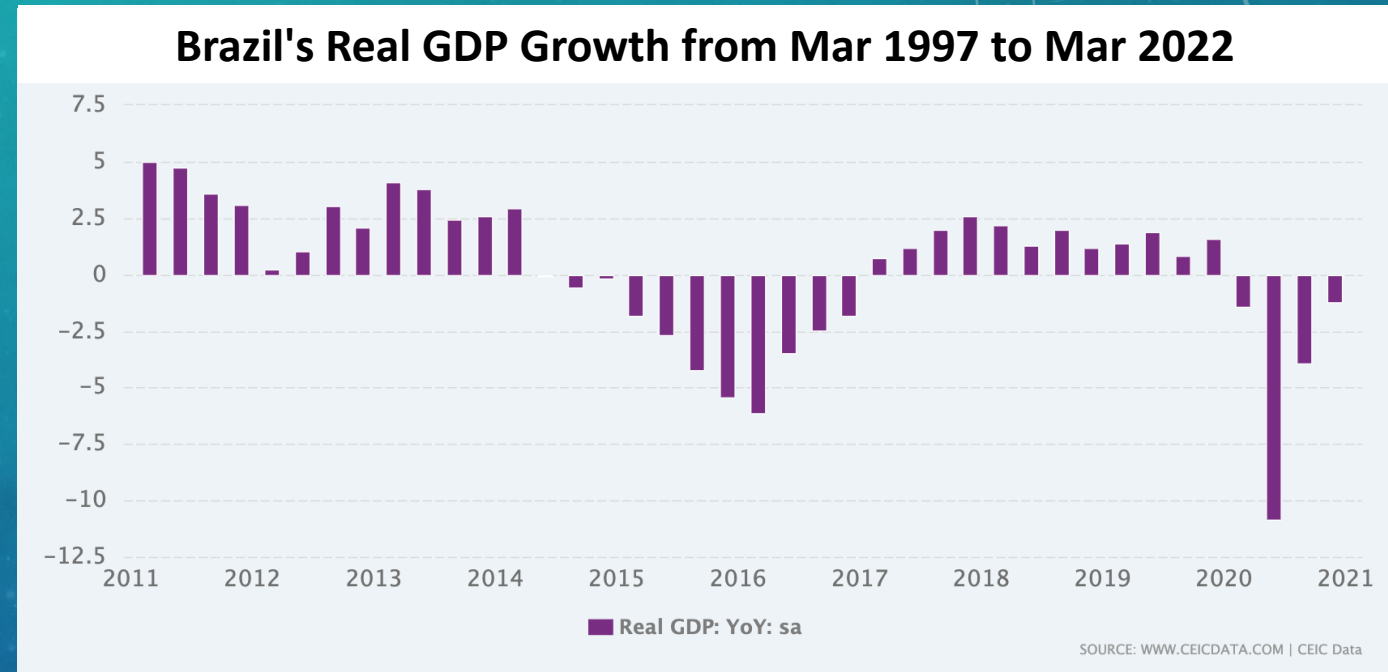
Main C-11 radiopharmaceuticals produced in the LA region.

# CHALLENGES AND OPPORTUNITIES

- The shortage of trained nuclear medicine physicians and the high cost of the PET-CT imaging system is restraining the market.
- There are about 10,000 board-certified radiologists in Brazil, which is inadequate for a country with 210 million inhabitants. Only 200 are nuclear medicine physicians.
- The lack of trained and qualified human resources is the limiting factor for the introduction of PET and new technologies.
- IAEA ARCAL projects (RLA6084, RLA6085) have been significantly contributing to strengthen human capacities and foster knowledge sharing in cyclotron operation, production, and QC of PET radiopharmaceuticals.
- IAEA has introduced a worldwide distance-assisted training program for NM technologists (online training resources covering basic sciences and clinical applications, with special attention to SPECT/CT and PET/CT).

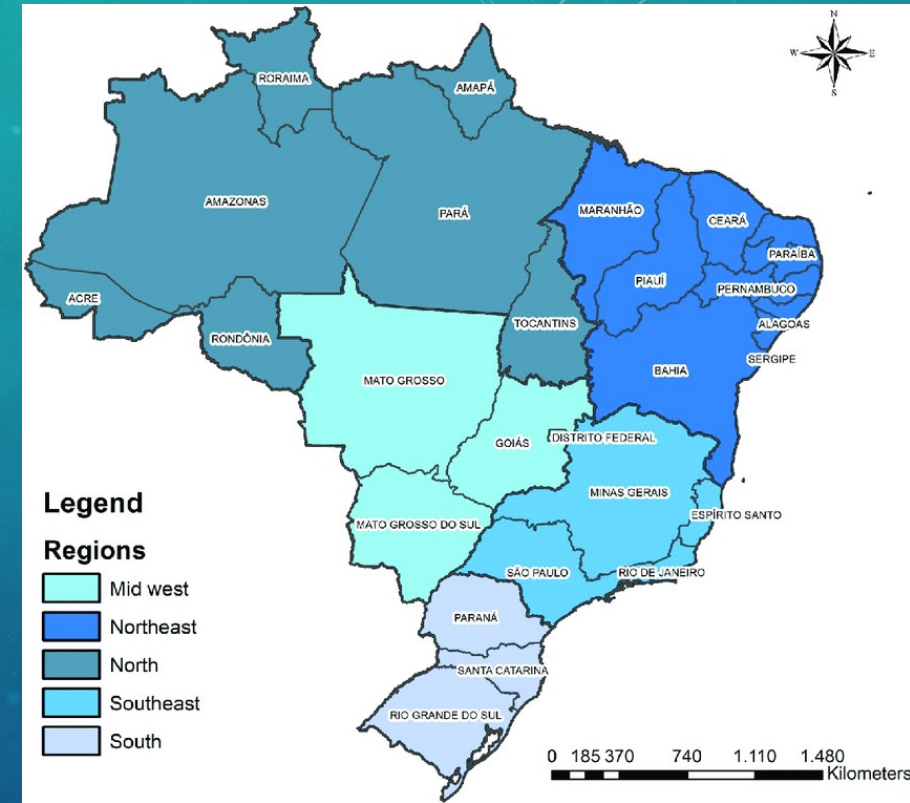
# CHALLENGES AND OPPORTUNITIES

- The performance of the Brazilian economy has endured many oscillations throughout its history.
- The size, cultural and financial differences between states are very high, is difficult to harmonize a social and a reimbursement policy.
- Large regional disparities exist in access to healthcare services, with poorer regions and lower socioeconomic population groups disadvantaged the most.
- Some Brazilian regions have similar conditions to the developed countries.



# CHALLENGES AND OPPORTUNITIES

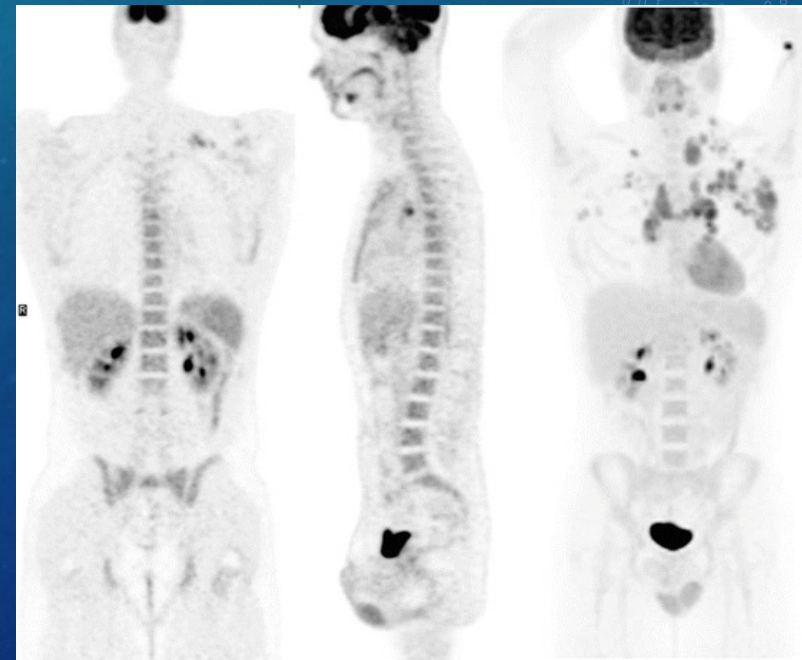
- There is an asymmetrical distribution of cyclotrons (16) and PET scanners (111) in Brazil (population around 210 million in 2019).
- Affordability of PET scanners are unequal:
  - North (4 PET/18,4 million = 0,22/million)
  - Northeast (30 PET/57,1 million = 0,05/million)
  - South (16 PET/30 million = 0,53/million)
  - Southeast (49 PET/88,4 million = 0,56/million)
  - Mid-Western (12 PET/16,3 million = 0,73/million)
- Opportunity to increase the number of PET facilities in the North and Northeast regions.





# CHALLENGES AND OPPORTUNITIES

- Small number of PET procedures reimbursed by public and private systems:
  - non-small cell lung cancer (SUS)
  - colorectal cancer (SUS)
  - Hodgkin's and non-Hodgkin's lymphomas (SUS)
  - solitary pulmonary nodule assessment
  - metastatic breast cancer
  - head and neck cancer
  - melanoma staging
  - esophageal cancer
- Cost of a PET scan (R\$ 3,500 e R\$ 4,000) is very high compared to minimum salary (R\$ 2,000/month).
- Increasing the availability could decrease the costs.



# CONCLUSIONS

- There is a clear need for the implementation of far-reaching PET and cyclotrons facilities that ensure access to the Brazilian population countrywide, especially in those regions in need.
- The lack of specialized staff (nuclear medicine physicians, medical physicists and radiochemists) requires investment in education and training (IAEA).
- There are difficulties in keeping maintenance contracts due to high costs, beyond shortage of local technical support.
- A good communication between the NM and referring physicians has been ensuring high-quality reports and guiding them on the most appropriate PET for a patient's particular need.
- Overcoming these difficulties can lead to the introduction and exploration of the full potential PET technology and the affordability for the needy patients.

# Medical Imaging & Data Analytics (MEDIIMA)

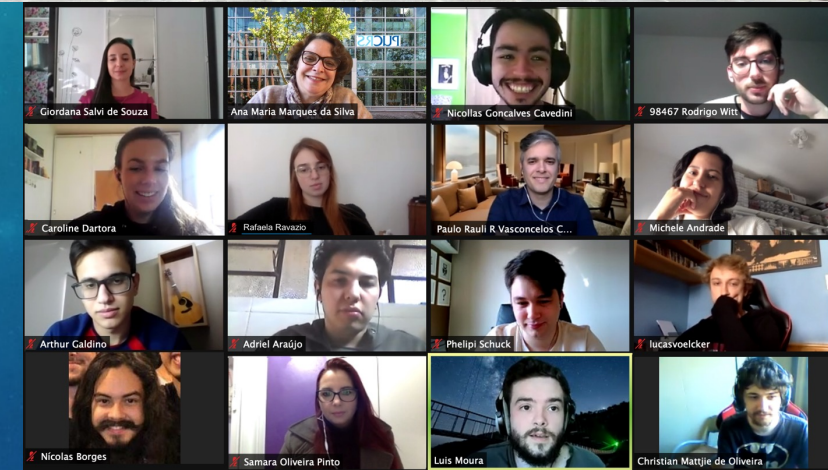


## Faculty

- Bruno Hocchegger
- Michele Alberton Andrade
- Ricardo Papaléo

## Students

- Adriel Silva de Araújo (DR)
- Andréia C. F. S. Fischer (DR)
- Christian Mattjie (DR)
- Dimitri Mantovani (IC)
- Giordana Salvi de Souza (DR)
- Luís Vinícius de Moura (MS)
- Maria Rosa Silva (IC)
- Nicollas Cavedini (DR)
- Rafaela Ravazio (MS)
- Samara Pinto (MS)



## Colaborators:

- Ana Claudia Patrocínio (UFU, Brazil)
- Caroline Machado Dartora (Karolinska, Suécia)
- Charalampos Tsoumpas (UMC Groningen, The Netherlands)
- Cristina Sebastião Matushita (InsCer, Brazil)
- Gert Lutersmma (UMC Groningen, The Netherlands)
- Isadora Lopes Alves (Brain Center, The Netherlands)
- Lucas Narciso (NWU, Canada)
- Michel Koole (KU Leuven, Belgium)
- Phelipi Nunes Schuck (Cornell, USA)
- Rudi Dierckx (UMC Groningen, The Netherlands)

Ana Maria Marques da Silva  
[anamarques@mediima.com](mailto:anamarques@mediima.com)