

# Regulation of cell therapies in Brazil

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ANVISA



Agência Nacional  
de Vigilância Sanitária

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# National Cell Therapy Network

Created in 2008

8 Cell Technology Centers



Ministry of Health  
Ministry of Science and Technology

Financial Support





# National Cell Therapy Network

Integrated network

Promotion of national scientific research

Development and improvement of techniques

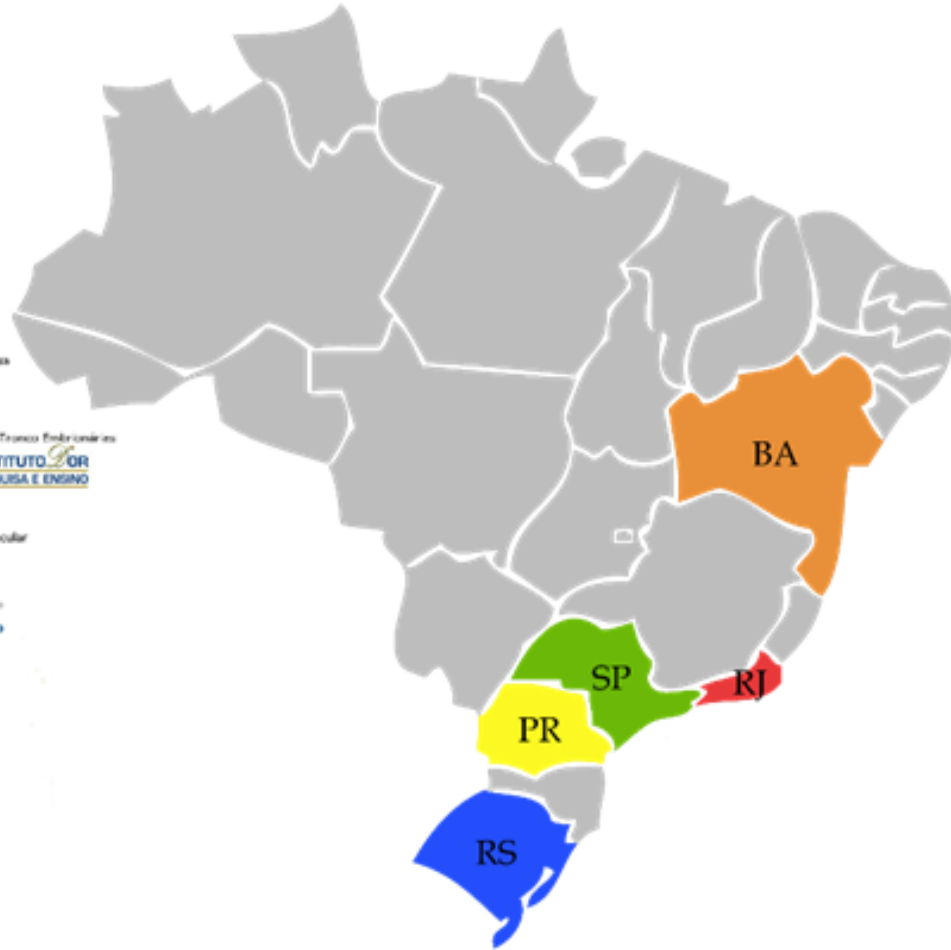
Exchange of knowhow

To issue relevant information



**RNTC**  
Rede Nacional de Terapia Celular

# National Cell Therapy Network



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# **Resolution n. 09/2011**

## **ANVISA**

# **Standard for the operation of**

## **Cell Technology Centers**

### **(CTC)**



# Resolution n. 09/2011

## Cell Technology Centers

- Premises, equipment and materials
- Documentation
- Quality requirements and quality control
- Biosafety
- Eligibility of donors and patients
- Collection
- Processing and storage
- Release for use
- Transportation

Good Cell Practices



# Resolution n. 09/2011

## Cell Technology Centers

- **Clinical Trials** – Approval by the Ethical Committees
- **Therapeutic use** – Acknowledgement by the Medical or Dental Federal Councils

Need to establish which advanced therapy products will be subject to pre-market approval by ANVISA



Cooperation with the Committee for Advanced Therapies-CAT and Medical and Dental Federal Councils



# Commercialization of human products

- ATMPs: marketing authorization allowed;
- Donation of the starting materials: safeguarded.



# ANVISA

## Regulatory Agenda

Advanced therapies products:

- Cell Therapies
- Tissue Engineering
- Gene therapy

# Advanced Therapies Medicinal Products- ATPMs

Advanced Cell  
Therapies

Tissue  
engineering

Gene  
Therapy

Extensive Manipulation- biological  
characteristics altered

*In vivo*

*Ex vivo*

Clinical Trials and Marketing Authorization



# ANVISA

## Regulatory Agenda

- Revision: Resolutions n. 56/2010 and 09/2011- Good Cell Practices;
- Standard for the approval of clinical trials with advanced therapies products in Brazil- Public Consult in 2017;
- Standard for the marketing authorization of advanced therapies products in Brazil

**Thank you!**

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