

# HTAI 2011

## HTA for Health Systems Sustainability

### **Registro Brasileiro de Ensaio Clínicos Brazilian Clinical Trials Registry Platform**

**Ricardo Gamarski, MD, MSc**

Knowledge Management General-Coordination  
Science and Technology Department  
Secretariat of Science and Technology and Strategic Inputs  
Ministry of Health of Brazil

Rio de Janeiro, June, 28<sup>th</sup> 2011

# HTAI 2011

## HTA for Health Systems Sustainability

OS21 – HTA RESEARCH INSTRUMENTS

**172 – BRAZILIAN CLINICAL TRIAL REGISTRY PLATFORM**

Ricardo Gamarski, MS, Brazil; Josué Laguardia, ICICT, Fundação Oswaldo Cruz, Brazil; Renato Murasaki, BIREME, Brazil; Luciano Ramalho, BIREME, Brazil; Rafael Soares, BIREME, Brazil

Rio de Janeiro, June, 28<sup>th</sup> 2011

# Brazilian Clinical Trials Registry

- Brazilian clinical trials were registered on Clinical Trials and ANZCTR
- Rebec was launched in december 2010

# Brazilian Clinical Trials Registry

- Publication bias
- Information available in portuguese
- Ongoing trials access
- Volunteers protection

# Brazilian Clinical Trials Registry

- Decit/MS, Ictict/Fiocruz and Paho initiative
- Bireme – software development
- Ictict/Fiocruz – runs the system, responsible for revisions

# Brazilian Clinical Trials Registry

## Development of the “Open Trials”



- Free Software
- Open source
- Available for download

# Brazilian Clinical Trials Registry

- Free registration
- Multilanguage(En, Pt, Es)
- 20 fields dataset
- Exporting data to ICTRP

# Brazilian Clinical Trials Registry

## Submission



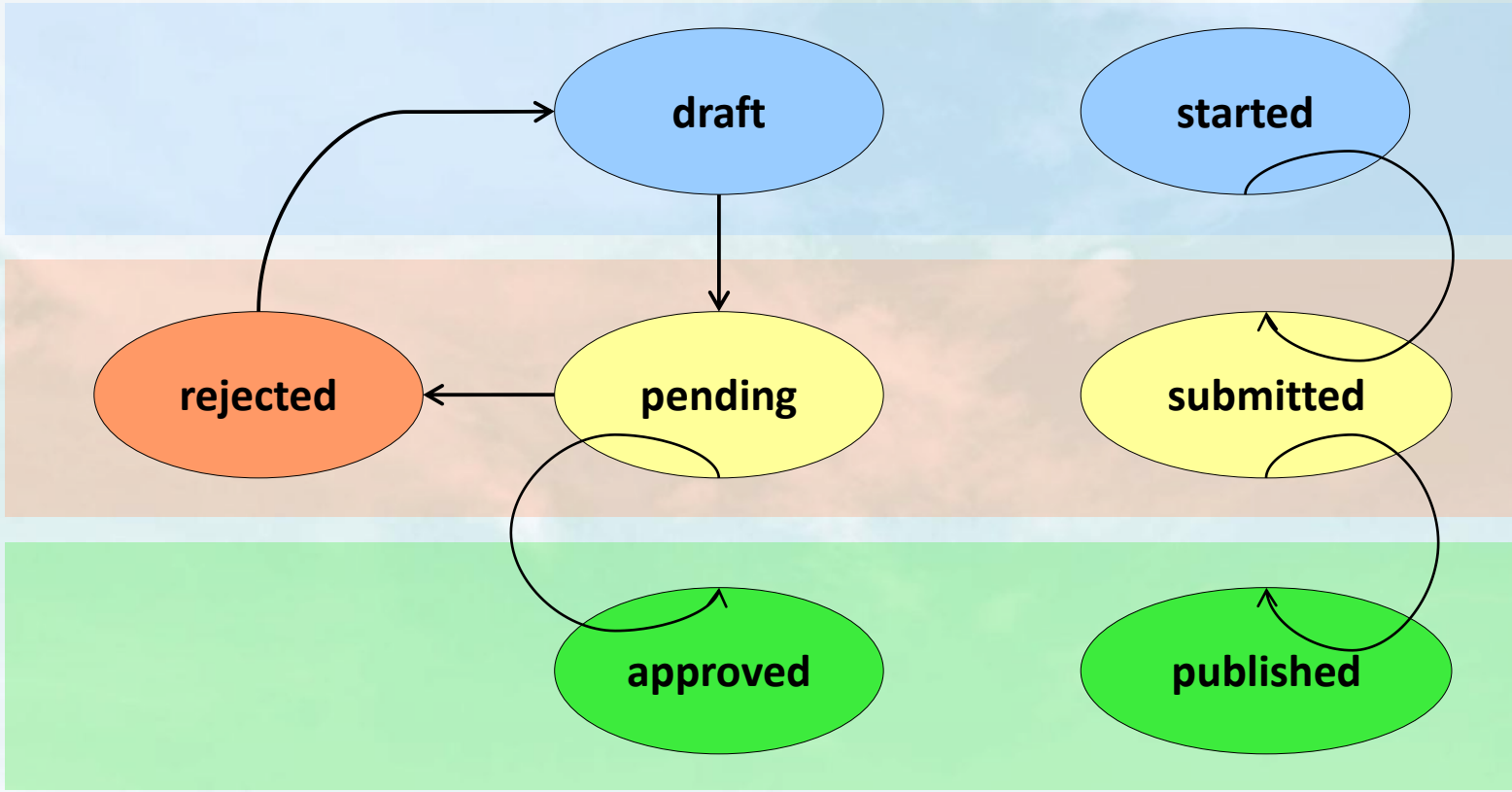
- After approval of the Ethics Committee / CONEP and before recruitment of first participant
- Integration with CONEP information system (Plataforma BRASIL)
- Import and export data in XML in 2 languages



# Brazilian Clinical Trials Registry

Clinical Trial in each language

Complete Register



# Brazilian Clinical Trials Registry

Saúde  
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**REGISTRO BRASILEIRO DE**  
**Ensaio Clínicos**

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SEARCH TRIALS

The Brazilian Clinical Trials Registry / Registro Brasileiro de Ensaio Clínicos (Rebec) is an open access virtual platform for registration of ongoing or concluded experimental e non-experimental studies on humans performed in Brazil and elsewhere. Rebec is a joint project of Brazilian Ministry of Health, Panamerican Health Organization (PAHO) and Oswaldo Cruz Foundation (FIOCRUZ). The Executive Committee of Rebec is composed of the aforementioned institutions and the National Health Surveillance Agency (ANVISA).

**Registered trials** NEW SUBMISSION

Use of infrared laser in vaginal delivery  
Primary Id Number: RBR-9zxb97

A Phase III Open Label, Randomized, 2 Arm Study of Ixabepilone Administered Every 21 Days Versus Paclitaxel Or...  
Primary Id Number: RBR-7spw98

A Randomized Double-Blinded Phase II Study of Carboplatin/Paclitaxel /CT-322 versus Carboplatin/Paclitaxel/Bevacizumab...  
Primary Id Number: RBR-48pb9h

**Scoreboard**

There are **12** registered trials.

There are **6** recruiting trial.

**Recruiting**

A Prospective Single Arm, Open-label, International, Multicenter Study to Evaluate the Safety, Efficacy and...

PREVER Study: Efficacy of Chlorthalidone associated with Amiloride versus Losartan in reducing blood pressure of...

PREVER Study: Efficacy of the combination of Chlorthalidone and Amiloride versus placebo in the prevention of...

Steroid Therapy for Autistic Children

A Randomized Double-Blinded Phase II Study of Carboplatin/Paclitaxel/CT-322 versus Carboplatin/Paclitaxel /Bevacizumab...

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**Latest Tweets**

Decit/SCITIE/MS faz apresentação sobre o Rebec hoje no XIX Curso da ABEC em Campinas. Conheça o Rebec em [www.ensaioclinicos.gov.br](http://www.ensaioclinicos.gov.br) 5 days ago

Acontece agora, virtualmente, a 24ª Reunião do Comitê Executivo do REBEC com o Ministério da Saúde, Fiocruz, Bireme. <http://bit.ly/1ecgovbr> 23 days ago

Follow us on Twitter!

8th annual meeting HTAi  
Rio de Janeiro 2011

SUS + Ministério da Saúde

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OpenTrials v1.0.22



# Brazilian Clinical Trials Registry

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USERNAME gamarski    SUBMISSIONS 003    TICKETS 000  
Profile Dashboard    LOGOUT

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Search trials

HOME / SUBMISSIONS / TRIAL SUMMARY [PREVIEW](#)

Part	Form name	Status (en)	Status (pt-br)
1	Trial Identification	Partial	Missing
2	Sponsors	Partial	Partial
3	Health Conditions	Missing	Missing
4	Interventions	Missing	Missing
5	Recruitment	Missing	Missing
6	Study Type	Missing	Missing
7	Outcomes	Missing	Missing
8	Contacts	Missing	Missing
9	Attachments	Partial	Partial

Submit for Review
 There are required fields missing.



# Brazilian Clinical Trials Registry

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**REGISTRO BRASILEIRO DE Ensaios Clínicos**

USERNAME: gamarski | SUBMISSIONS: 003 | TICKETS: 000 | Profile Dashboard | LOGOUT

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SEARCH trials

SUMMARY | TRIAL IDENTIFICATION | SPONSORS | HEALTHCARE | BIDDING | RECRUITMENT | STUDY TYPE | OUTCOMES | CONTACTS | ATTACHMENTS | REVIEW

### Trial Identification (\*) Required fields

Scientific Title: (*)	Portuguese	English
		teste maio
Scientific Acronym:	Portuguese	English
Scientific Acronym Expansion:	Portuguese	English
Public Title:	Portuguese	English
Acronym:	Portuguese	English
Acronym Expansion:	Portuguese	English
UTN Number: (*)	U1234-2222-2222	

### Secondary Identifying Numbers

Issuing Authority:	<input type="text"/>
Secondary Id Number:	<input type="text"/>
Delete:	<input type="checkbox"/>

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# Registro Brasileiro de Ensaios Clínicos

[www.ensaiosclinicos.gov.br](http://www.ensaiosclinicos.gov.br) / [www.ec.gov.br](http://www.ec.gov.br)

The screenshot shows the homepage of the Registro Brasileiro de Ensaios Clínicos (Rebec). The header features the logo and name of the registry, along with a login section for users and a search bar. The main content area is divided into two columns. The left column contains a 'Registered trials' section with a 'NEW SUBMISSION' button and a list of trials, including 'Use of infrared laser in vaginal delivery' and 'A Phase III Open Label, Randomized, 2 Arm Study of Ixabepilone Administered Every 21 Days Versus Paclitaxel Or...'. The right column features a 'Scoreboard' section with statistics on registered and recruiting trials, a 'Recruiting' section listing ongoing studies, and a 'Latest Tweets' section with a social media follow button. The footer includes logos for the Brazilian Ministry of Health, SUS, and the Brazilian Government, along with the OpenTrials logo and version number.

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Follow us on Twitter!

OpenTrials v1.-0.22

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## HTA for Health Systems Sustainability



# Thank you!!!

**Ricardo Gamarski, MD, MSc**

CGGC/Decit/SCTIE/MS

[ricardo.gamarski@saude.gov.br](mailto:ricardo.gamarski@saude.gov.br)

+55(61)3315-3466

Rio de Janeiro, June, 28<sup>th</sup> 2011