



**Tuesday - June 16<sup>th</sup>**  
**HIAE - CESAS ROOM**

**Clinical Research In Practice: Focus On Clinical Trials Course**  
**June, 15th 2015**

**Chairmen:** Thiago Domingos Corrêa and Marcelo Katz

07h30 – 08h00 Registration

### **Module I: Fundamentals of trial design**

**08:00 – 08:20 Defining the research question**  
Alexandre Holthausen Campos

**08:20 – 08:40 Writing a good and feasible protocol**  
Ricardo Luiz Cordioli

**08:40 – 09:00 Designing observational studies**  
Jorge Ibrain Figueira Salluh

**09:00 – 09:20 Drugs development and the studies phases**  
Leonardo Lima Rocha

**09:20 – 09:40 Equivalence and non-inferiority clinical trials**  
Marcelo Katz

09:40 – 10:00: Discussion and questions

10:00 – 10:30: Break

### **Module II: Randomized controlled trials in practice**

**10:30 – 10:50 Defining the right population and endpoints**  
Jorge Ibrain Figueira Salluh

**10:50 – 11:10: Basic designs, randomization and blinding**  
Thiago Domingos Correa

**11:10 – 11:30 Strategies for recruitment and dropout prevention**  
Marcio Soares



**11:30 – 11:50 Intention to treat or per protocol analysis?**  
Thiago Domingos Correa

**11:50 – 12:10 Designs for cost-effectiveness analysis**  
Danilo Teixeira Noritomi

12:10 – 12:30: Discussion and questions

12:30 – 13:30: Break

### **Module III: Research in the ICU: special issues**

**13:30 – 13:50 Deferred consent: why and when?**  
Adriano José Pereira

**13:50 – 14:10 The challenges of multicenter trials**  
Alexandre Biasi Cavalcanti

**14:10 – 14:30 When to stop early for efficacy and safety?**  
Ary Serpa Neto

**14:30 – 14:50 New trends: pragmatic trials**  
Alexandre Biasi Cavalcanti

14:50 – 15:00: Discussion and questions

15:00 – 15:30: Break

### **Module IV: The research infrastructure**

**15:30 – 15:50 Building up a research team**  
Otávio Berwanger

**15:50 – 16:10 The role of DSMB and the clinical event adjudication committee**  
Otávio Berwanger

**16:10 – 16:30 Funding: opportunities in Brazil**  
Aline Pacifico Rodrigues

**16:30 – 16:50 Authorship: how to avoid a dispute**  
Guilherme de Paula Pinto Schettino

**16:50 – 17:10 Manuscript writing: how to avoid mistakes**



Marcio Soares

17:10 – 17:30: Discussion and final considerations