Discipline MCP5885
Understanding Clinical Research Based on Real Studies

Concentration area: 5131

Creation: 25/10/2017

Activation: 26/10/2017

Credits: 2

Workload:

<table>
<thead>
<tr>
<th>Theory (weekly)</th>
<th>Practice (weekly)</th>
<th>Study (weekly)</th>
<th>Duration</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>6</td>
<td>4</td>
<td>5</td>
<td>2 weeks</td>
<td>30 hours</td>
</tr>
</tbody>
</table>

Professors:

Roberto Rocha Corrêa Veiga Giraldez

Jose Eduardo Krieger

Patricia Oliveira Guimarães

Objectives:

To interpret clinical studies, using real contemporary studies to illustrate the main topics of clinical research. To discuss basic aspects of trial design and biostatistics.

Rationale:

In the current era, the results of large international randomized clinical trials guide most of the decisions in clinical practice in cardiology. Therefore, it is essential for health care providers to understand the basic methodologic aspects of clinical research in order to interpret its results. This course aims to support the development of the scientific thinking and the implementation of clinical research projects in this institution. International speakers with extensive experience in conducting different types of studies will collaborate in this course. The lectures will be given in English through video-conference, followed by a period of discussion when students will have the opportunity to interact with the speakers and ask questions.

Content:

1. Basic aspects of trial design (Karen Pieper, MS; Duke University-United States) 2. How to interpret a scientific manuscript? (Renato D. Lopes, MD, MHS, PhD; Duke University-United States) 3. Confounding (Karen Pieper, MS; Duke University-United States) 4. The choice of composite outcomes (Renato D. Lopes, MD, MHS, PhD; Duke University-United States) 5. Monitoring Efficacy, Safety and Futility (Kenneth Mahaffey, MD; Stanford University-United States) 6. Meta-analysis and observational research (Robert Giugliano, MD; Harvard Medical School-United States) 7. Subgroup analysis and multiple testing (Patrícia Guimarães, MD, PhD, InCor - University of São Paulo) 8. Statistical terms (Roberto Rocha C.V. Giraldez, MD, PhD, InCor - University of São Paulo)
Type of Assessment:

Frequency and participation in lectures. Written critical analysis of a clinical trial that will be given at course start.

Bibliography:

2. Lawrence M. Friedman, Curt D. Furberg, David L. DeMets, David M. Reboussin, Christopher B. Granger. Fundamentals of Clinical Trials. 5th edition. 2015

Languages taught:

English